REGIONE CAMPANIA
AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE E DI ALTA SPECIALIZZAZIONE
"SANT'ANNA E SAN SEBASTIANO"
CASERTA

Determina Dirigenziale N. 115 del 10/02/2025

Proponente: Il Direttore UOC PROVVEDITORATO ED ECONOMATO

Oggetto: PROCEDURA APERTA PER L'AFFIDAMENTO DELLA FORNITURA DI SUTURATRICI MECCANICHE, CLIPS E SISTEMI DI FISSAGGIO PER CHIRURGIA APERTA E LAPAROSCOPICA - ADESIONE AZIENDALE EX DEL. DEL D.G. N. 1008/2023 - LOTTO N. 31 - 32 - AGGIORNAMENTO TECNOLOGICO / AFFIANCAMENTO - DITTA JOHNSON & JOHNSON MEDICAL S.P.A.

PUBBLICAZIONE
In pubblicazione dal 10/02/2025 e per il periodo prescritto dalla vigente normativa in materia (art.8 D.Lgs 14/2013, n.33 e smi)

ESECUTIVITA'
Atto immediatamente esecutivo

TRASMISSIONE
La trasmissione di copia della presente Deliberazione è effettuata al Collegio Sindacale e ai destinatari indicati nell'atto nelle modalità previste dalla normativa vigente. L'inoltro alle UU. OO. aziendali avverrà in forma digitale ai sensi degli artt. 22 e 45 D.gs. n° 82/2005 e s.m.i. e secondo il regolamento aziendale in materia.

UOC AFFARI GENERALI
Direttore Eduardo Chianese

ELENCO FIRMATARI

Teresa Capobianco - UOC PROVVEDITORATO ED ECONOMATO

Per delega del Direttore della UOC AFFARI GENERALI, il funzionario Mauro Ottaiano

Il presente atto, in formato digitale e firmato elettronicamente, costituisce informazione primaria ed originale ai sensi dei combinati disposti degli artt. 23-ter, 24 e 40 del D.Lgs. n. 82/2005. Eventuale riproduzione analogica, costituisce valore di copia semplice a scopo illustrativo.

Oggetto: PROCEDURA APERTA PER L'AFFIDAMENTO DELLA FORNITURA DI SUTURATRICI MECCANICHE, CLIPS E SISTEMI DI FISSAGGIO PER CHIRURGIA APERTA E LAPAROSCOPICA - ADESIONE AZIENDALE EX DEL. DEL D.G. N. 1008/2023 - LOTTO N. 31 - 32 - AGGIORNAMENTO TECNOLOGICO / AFFIANCAMENTO - DITTA JOHNSON & JOHNSON MEDICAL S.P.A.

Il Direttore UOC PROVVEDITORATO ED ECONOMATO

A conclusione di specifica istruttoria, descritta nella narrazione che segue, si rappresenta che ricorrono i presupposti finalizzati all'adozione del presente provvedimento, ai sensi dell'art. 2 della Legge n. 241/1990 e s.m.i. e, in qualità di responsabile del procedimento, dichiara l'insussistenza del conflitto di interessi, ai sensi dell'art. 6bis della legge 241/90 e s.m.i

PREMESSO CHE

- So.re.sa. S.p.A. con Determinazione del Direttore Generale n. 90 del 27/04/2023 ha aggiudicato la "*procedura aperta per l'affidamento della fornitura di suturatrici meccaniche, clips e sistemi di fissaggio per chirurgia aperta e laparoscopica* occorrenti alle Aziende del SSR della Regione Campania;
- con Deliberazione del D.G. n. 1008 del 10/11/2023, qui integralmente richiamata e trascritta, questa Aorn ha aderito all'Accordo Quadro SO.RE.SA S.p.A. per la fornitura quadriennale di suturatrici meccaniche, clips e sistemi di fissaggio per chirurgia aperta e laparoscopica, aderendo, tra l'altro al lotto 31 "Suturatrici lineari taglia e cuci con stelo rotante a 360° 45 mm e relativi caricatori" e 32 "Suturatrici lineari taglia e cuci con stelo rotante a 360° 60 mm e relativi caricatori" in capo alla ditta JOHNSON & JOHNSON MEDICAL S.P.A., in qualità di primo aggiudicatario;
-

RILEVATO CHE

- la SO.RE.SA., con nota Prot. n. 0015054 del 26/09/2024 (**allegato n. 1**) - relativamente alla fornitura di che trattasi - ha autorizzato, previa richiesta della Ditta JOHNSON & JOHNSON MEDICAL S.P.A., (già Allegato 1), l'affiancamento del:

- ATTUALE SITUAZIONE

LOTTO	VOCE	DESCRIZIONE LOTTO	CODICE PRODOTTO
31	1	Suturatrici lineari taglia e cuci lunghezza linea di sutura da 45 mm	PCEE45A-PSEE45A-PLEE45A
	2	Caricatori per suturatrici lineari monopaziente,	GST45W

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		taglia e cuci	

Con:

NUOVI CODICI

LOTTO	VOCE	DESCRIZIONE NUOVO LOTTO	VECCHIO CODICE (privo di caricatore)	NUOVO CODICE (con caricatore)
31	1-2	Suturatrice lineare taglia e cuci lunghezza di sutura da 45 mm, con articolazione a batteria (codice ECH45C) e caricatore a corredo (codice GST45W)	PCEE45A	CKECH45CW
	1-2	Suturatrice lineare taglia e cuci lunghezza di sutura da 45 mm, con articolazione a batteria (codice ECH45S) e caricatore a corredo (codice GST45W)	PSEE45A	CKECH45SW
	1-2	Suturatrice lineare taglia e cuci lunghezza di sutura da 45 mm, con articolazione a batteria (codice ECH45L) e caricatore a corredo (codice GST45W)	PLEE45A	CKECH45LW

- ATTUALE SITUAZIONE

32	1	Suturatrici lineari taglia e cuci lunghezza linea di sutura da 60 mm	PCEE60A-PSEE60A-PLEE60A
	2	Caricatori per suturatrici lineari monopaziente, taglia e cuci	GST60W

Con:

NUOVI CODICI

LOTTO	VOCE	DESCRIZIONE NUOVO LOTTO	VECCHIO CODICE (privo di caricatore)	NUOVO CODICE (con caricatore)
32	1-2	Suturatrice lineare taglia e cuci	PCEE60A	CKECH60CW

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		lunghezza di sutura da 60 mm, con articolazione a batteria (codice ECH60C) e caricatore a corredo (codice GST60W)		
	1-2	Suturatrice lineare taglia e cuci lunghezza di sutura da 60 mm, con articolazione a batteria (codice ECH60S) e caricatore a corredo (codice GST60W)	PSEE60A	CKECH60SW
	1-2	Suturatrice lineare taglia e cuci lunghezza di sutura da 60 mm, con articolazione a batteria (codice ECH60C) e caricatore a corredo (codice GST60W)	PLEE60A	CKECH60LW

CONSIDERATO CHE *"l'aggiornamento tecnologico - affiancamento"* di che trattasi non comporta alcuna spesa aggiuntiva per l'Azienda, rimanendo invariate le condizioni economiche e di fornitura;
RITENUTO, pertanto, di prendere atto della richiesta di *aggiornamento tecnologico – affiancamento*, autorizzata dalla SORESA S.p.A. (già Allegato n.1) - proposta dalla Ditta JOHNSON & JOHNSON MEDICAL S.P.A., aggiudicataria dei Lotti nn. 31 - 32 della "Procedura aperta per l'affidamento della fornitura di suturatrici meccaniche, clips e sistemi di fissaggio per chirurgia aperta e laparoscopica occorrenti alle Aziende del SSR della Regione Campania", come riportato in premessa e qui integralmente trascritto;
ESAMINATA tutta la documentazione innanzi richiamata allegata alla presente ed in atti giacente;
ATTESTATO CHE la presente determinazione è formulata previa istruttoria ed estensione conformi alla normativa legislativa vigente in materia;

DETERMINA

per le causali in premessa, che qui si intendono integralmente richiamate e trascritte, di:
I - PRENDERE ATTO – relativamente alla fornitura in questione, della richiesta di aggiornamento tecnologico – affiancamento, autorizzata dalla SORESA S.p.A. (già Allegato n.1) - proposta dalla Ditta JOHNSON & JOHNSON MEDICAL S.P.A., aggiudicataria dei Lotti nn. 31 - 32 della "Procedura aperta per l'affidamento della fornitura di suturatrici meccaniche, clips e sistemi di

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fissaggio per chirurgia aperta e laparoscopica occorrenti alle Aziende del SSR della Regione Campania", come riportato in premessa e qui integralmente trascritto;
II – PRECISARE CHE l'aggiornamento tecnologico - affiancamento in parola non comporta alcuna spesa aggiuntiva per l'Azienda, restando invariate le condizioni economiche e di fornitura;
III - TRASMETTERE copia del presente atto al Collegio Sindacale, come per legge, ed alla UOC Farmacia Ospedaliera.

Il funzionario
Dott.ssa Maria Cioffi

Il Direttore UOC Provveditorato ed Economato
Dr.ssa Teresa Capobianco

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autorizzazione aggiornamento tecnologico- Procedura aperta per l'affidamento della "Fornitura di Suturatrici Meccaniche, Clips e Sistemi di Fissaggio per Chirurgia aperta e laparoscopica occorrenti alle Aziende del SSR della Regione Campania-

Da **arealegale@pec.soresa.it** <arealegale@pec.soresa.it>

A **provveditorato@pec.aslavellino.it** <provveditorato@pec.aslavellino.it>,
area.provveditorato@pec.aslbenevento.it <area.provveditorato@pec.aslbenevento.it>,
servizio.provveditorato@pec.asicaserta.it <servizio.provveditorato@pec.asicaserta.it>,
acquisizione.beni@pec.asIna1centro.it <acquisizione.beni@pec.asIna1centro.it>,
provveditorato@pec.asInapoli2nord.it <provveditorato@pec.asInapoli2nord.it>,
sabs@pec.asInapoli3sud.it <sabs@pec.asInapoli3sud.it>,
provveditore@pec.asIsalerno.it <provveditore@pec.asIsalerno.it>,
provveditorato@pec.istitutotumori.na.it <provveditorato@pec.istitutotumori.na.it>,
abse.aocardarelli@pec.it <abse.aocardarelli@pec.it>,
provveditorato.santobono@pec.it <provveditorato.santobono@pec.it>,
provveditorato.ospedalideicolli@pec.it <provveditorato.ospedalideicolli@pec.it>,
provveditorato.economato@pec.sangiovannieruggi.it
<provveditorato.economato@pec.sangiovannieruggi.it>, **ufficio.gare@pec.aornmoscati.it**
<ufficio.gare@pec.aornmoscati.it>, **provveditorato@pec.ao-rummo.it**
<provveditorato@pec.ao-rummo.it>, **provveditorato@ospedalecasertapec.it**
<provveditorato@ospedalecasertapec.it>, **protocollo.policliniconapoli.it@pec.it**
<protocollo.policliniconapoli.it@pec.it>, **respprovveconomato.aou@pec.it**
<respprovveconomato.aou@pec.it>, **JOHNSONEJOHNSONMEDICAL@POSTECERT.IT**
<JOHNSONEJOHNSONMEDICAL@POSTECERT.IT>

Data giovedì 26 settembre 2024 - 11:23

Con la presente si trasmette SoReSa-0015054-2024 26-09-2024 con i relativi allegati.
Distinti saluti.

SORESA
Società Regionale per la Sanità S.p.A.

Direzione Affari Legali

SRA 15054-2024autorizzazione_aggiornamento_tecnologico (6).pdf
Proposta_affiancamento_ID_GARA_8705111.pdf
87644-global-surgeon-opinion-on-the-imp...endocutters-across-specialties_(1).pdf
ECHELON_3000_STAPLER_REV_C.pdf
EM_ETH_STAP_304772_Huang_2022.pdf
scheda_tecnica_suturatrice_echelon_3000_45mm.pdf
Scheda_tecnica_Suturatrice_ECHELON_3000_60mm.pdf

SoReSa

L' art. 23 del Codice dell'Amministrazione Digitale (Decreto Legislativo 7 marzo 2005, n. 82 e s.m.i.), riconosce alle copie analogiche di documenti informatici (es. la stampa di un certificato, un contratto, ecc.) la stessa efficacia probatoria dell'originale informatico da cui sono tratti se la loro conformit non viene espressamente disconosciuta (in giudizio). Diverso il caso in cui la conformit all'originare informatico, in tutte le sue componenti, sia attestata da un pubblico ufficiale autorizzato. In questo caso, infatti, per negare alla copia analogica di documento informatico la stessa efficacia probatoria del documento sorgente si rende necessaria la querela di falso.

Questo regime, di carattere generale, incontra alcune deroghe rispetto alle copie analogiche di documenti amministrativi informatici.

L'art. 23-ter del CAD prevede che sulle copie analogiche di documenti amministrativi informatici possa essere apposto un contrassegno a stampa (detto anche timbro digitale o glifo) che consente di accertare la corrispondenza tra le copie analogiche stesse e l'originale informatico (in esso deve essere codificato, infatti, il documento informatico o le informazioni necessarie a verificarne la corrispondenza all'originale in formato digitale). La verifica avviene grazie ad appositi software che leggono le informazioni contenute nel timbro digitale. I software necessari per l'attivit di verifica devono essere gratuiti e messi liberamente a disposizione da parte delle amministrazioni.

Copia conforme di un documento amministrativo informatico formata ai sensi dell'articolo 23-ter, comma 5 del CAD.
Il presente contrassegno digitale Datamatrix contiene informazioni utili alla verifica della corrispondenza del documento all'originale digitale conservato dall'amministrazione proprietaria dello stesso.
Il contrassegno pu essere letto con qualsiasi applicazione in grado di decodificare il formato Datamatrix e con gli smartphone dei principali costruttori.
In alternativa possibile collegarsi al sistema DgsWebOS dell'amministrazione e ricercare dopo l'autenticazione il documento

Impronta del documento digitale originale: ba9b19fb6d953bff1462f42a2408521f
Identificativo del documento digitale originale: 596971
Protocollo: SoReSa-0015054-2024 26-09-2024 11:10:00

Documento generato dal sistema DgsWebOS in data: 26-09-2024 11:15:40

Società Regionale per la Sanità S.P.A.

Ai Sig.ri Direttori Generali
Ai Sig.ri Provveditori
AA.SS.LL., AA.OO., AA.OO.UU., IRCSS
a mezzo pec

e p.c.

JOHNSON & JOHNSON MEDICAL S.P.A.
A mezzo pec: johnsonejohnsonmedical@postecert.it

Oggetto: Autorizzazione aggiornamento tecnologico . Procedura aperta per l'affidamento della "Fornitura di Suturatrici Meccaniche, Clips e Sistemi di Fissaggio per Chirurgia aperta e laparoscopica occorrenti alle Aziende del SSR della Regione Campania- ID GARA:8705111

Con riferimento all' Accordo Quadro in oggetto

vista la richiesta di autorizzazione aggiornamento tecnologico- affiancamento, presentata dalla società **JOHNSON & JOHNSON MEDICAL S.P.A.** nell'ambito della suddetta fornitura ed acquisita al protocollo interno con n. SoReSa-0010614-2024 04-07-2024

alla luce dell'istruttoria espletata ed acquisito il parere tecnico favorevole circa l'aggiornamento tecnologico proposto dalla Ditta

si autorizza, secondo le previsioni del Capitolato Tecnico di gara, alle medesime condizioni economiche contrattuali, l'aggiornamento tecnologico-affiancamento come da richiesta che costituisce parte integrante e sostanziale della presente autorizzazione.

In allegato:

- Istanza di autorizzazione aggiornamento tecnologico.
- Schede tecniche

Distinti saluti.

So.Re.Sa. S.p.A.
Il Responsabile per l'esecuzione del contratto
Avv. Gianmarco Massa

Avv. Fabio Aprea
Direttore Affari Legali

SoReSa

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Il contrassegno pu essere letto con qualsiasi applicazione in grado di decodificare il formato Datamatrix e con gli smartphone dei principali costruttori.
In alternativa possibile collegarsi al sistema DgsWebOS dell'amministrazione e ricercare dopo l'autenticazione il documento

Impronta del documento digitale originale: bfed16393699fa14574c7a7097e1733e
Identificativo del documento digitale originale: 582825
Protocollo: SoReSa-0010614-2024 04-07-2024 09:31:22

Documento generato dal sistema DgsWebOS in data: 04-07-2024 09:46:48

SISTEMA DI GESTIONE QUALITÀ CERTIFICATI
CQY CERTIQUALITY
UNI EN ISO 9001:2015
UNI CEI EN ISO 13485:2016
SGS

Johnson&Johnson
MEDTECH

Spett.le
So.Re.Sa. S.p.A.
Centro Direzionale Isola F9 - 80143 Napoli

All' Att.ne di
Ing. A. Di Bello
Dott.ssa Giuseppina Porfido
Avv. Gianmarco Massa
Dott. Fabio Aprea

Pomezia, 03.07.2024
OGGETTO: Procedura Aperta per l'affidamento della "*Fornitura di Suturatrici Meccaniche, Clips e Sistemi di Fissaggio per Chirurgia Aperta e Laparoscopica Occorrenti alle Aziende del SSR della Regione Campania*" - ID GARA: 8705111

Proposta di affiancamento ai sensi dell'art. 6 Aggiornamento Tecnologico

Spett.le So.Re.Sa.,
La **Johnson & Johnson Medical S.p.A.** con sede legale in Via del Mare, 56 - 00071 Pomezia (RM)- N. Iscrizione Registro A.E.E. IT08020000000224, N. Iscrizione Registro Pile IT09060P00000270, in riferimento all'oggetto

PREMESSO CHE

- con deliberazione n. 90 del 27/04/2023, a Johnson & Johnson Medical S.p.A. è stata affidata la fornitura dei prodotti oggetto, rispettivamente, dei **Lotti nn. 31** (Suturatrici lineari taglia e cuci con stelo rotante a 360° 45 mm e relativi caricatori) e **32** (Suturatrici lineari taglia e cuci con stelo rotante a 360° 60 mm e relativi caricatori) della procedura in oggetto;
- entrambi i lotti prevedono due voci, una relativa alla suturatrice e l'altra relativa ai caricatori associati in quanto, come noto,
  - la suturatrice, attualmente fornita senza alcuna ricarica, deve essere necessariamente utilizzata in combinazione con almeno un caricatore; e
  - ciascuna suturatrice può essere utilizzata solo in associazione con il proprio caricatore dedicato (incluso dunque nello stesso lotto della suturatrice);
  - Il numero di caricatori necessari al completamento delle diverse procedure chirurgiche è fortemente variabile da un minimo di 1 (senza cui la suturatrice non potrebbe essere usata) ad un massimo di 7-8 in base alla tipologia di tessuto ed alla tecnica chirurgica.
- in relazione a ciascuno dei lotti sopra richiamati, solo l'offerta tecnica di Johnson & Johnson Medical S.p.A. è risultata utilmente collocata in graduatoria in quanto le offerte presentate da altri operatori concorrenti all'aggiudicazione dei due lotti non hanno superato la cd. "soglia di sbarramento" qualitativa; pertanto, nonostante la procedura in oggetto prevedesse l'affidamento della fornitura in accordo quadro multi-fornitore

senza rilancio competitivo, nei due lotti in questione (nn. 31 e 32) solo Johnson & Johnson Medical S.p.A. è risultata (ed è tuttora) aggiudicataria della relativa fornitura;

- successivamente alla presentazione dell'offerta nella procedura in oggetto, Johnson & Johnson Medical S.p.A. ha immesso in commercio in Italia suturatrici innovative, del tipo di quelle aggiudicati ai lotti nn. 31 e 32, che pertanto la scrivente intende proporre in affiancamento ai sensi di quanto previsto da specifica previsione della *lex specialis* della procedura in oggetto;
- le nuove suturatrici saranno disponibili per la commercializzazione alle strutture sanitarie afferenti alla Vs spett.le Centrale di Committenza a partire dal mese di settembre 2024.

CONSIDERATO CHE

ai sensi dall' *art. 6 Aggiornamento Tecnologico* del Capitolato Tecnico, è prevista la possibilità di presentare prodotti tecnologicamente aggiornati e migliorativi rispetto a quelli aggiudicati in gara, nella fattispecie:

Qualora, in corso di fornitura, vengano apportate variazioni sostanziali nella produzione di quanto aggiudicato o vengano introdotti sul mercato prodotti sostitutivi o dovesse essere commercializzato un prodotto tecnologicamente aggiornato e migliorativo rispetto a quello aggiudicato, la Ditta aggiudicataria, previa autorizzazione dell'Amministrazione Competente, si impegna a immettere nella fornitura il nuovo prodotto, alle medesime condizioni contrattuali.
Le variazioni dei prodotti in corso di fornitura possono consistere in:

- *Affiancamento di prodotti più aggiornati ai prodotti aggiudicati che l'Operatore economico continua comunque a fornire:*
- *Sostituzione di una parte o della totalità dei Dispositivi aggiudicati.*

Ai fini dell'ottenimento dell'autorizzazione all'affiancamento o alla sostituzione dei prodotti in corso di fornitura la Ditta aggiudicataria dovrà far prevenire a So.Re.Sa. S.p.A. una relazione tecnico/scientifica, accompagnata da adeguata documentazione a supporto, in cui si evincono i vantaggi dell'aggiornamento tecnologico proposto in relazione alla variazione di una o più caratteristiche che differenziano il prodotto proposto dal prodotto aggiudicato in Gara.

Tutto quanto sopra premesso e considerato, Johnson & Johnson Medical S.p.A.

PROPONE

ai sensi e per gli effetti del richiamato art. 6 del Capitolato Tecnico, l'affiancamento – a partire dal mese di settembre 2024 - ai lotti nn. 31 e 32 della procedura in oggetto di nuovi prodotti alle medesime condizioni contrattuali di quelle dei prodotti omologhi offerti (e aggiudicati) in gara.

Considerato che la nuova suturatrice proposta, come quelle aggiudicate alla scrivente ai lotti 31 e 32, prevede necessariamente l'utilizzo di un caricatore prima dell'azionamento e che il caricatore è lo stesso di quello già incluso nel lotto (oggetto di specifica voce), l'affiancamento consiste nel consentire alle strutture utilizzatrici di indicare in ordine **un unico codice che comprende sia una suturatrice sia a corredo il relativo caricatore dedicato, comunque**

necessario per la prima attivazione. Si fa presente che, poiché il caricatore resta immutato e che quest'ultimo è necessario per ogni utilizzo della suturatrice, la proposta avanzata con la presente non modifica né altera le attuali condizioni contrattuali posto che le strutture utilizzatrici delle suturatrici ordinano queste ultime sempre necessariamente insieme al proprio caricatore dedicato. Pertanto, la proposta di affiancamento consiste nella creazione di un unico codice identificativo che contiene al proprio interno una suturatrice e il relativo caricatore a corredo così che le strutture utilizzatrici dovranno indicare nel relativo ordine solo tale codice per ricevere sia la suturatrice (nella versione più tecnologicamente avanzata) sia il relativo caricatore necessario al primo azionamento. Nulla cambia per le ulteriori ricaricariche eventualmente necessarie, rispetto a quanto oggetto di aggiudicazione. Naturalmente, a livello economico, non si verifica alcun incremento di costo posto che il codice identificativo comprendente suturatrice e caricatore a corredo sarebbe commercializzato al prezzo pari alla somma dei prezzi di aggiudicazione di suturatrice e caricatore.

Ci si permette di rappresentare di seguito in modalità grafica – tramite ausilio di tabelle – la descrizione del meccanismo proposto.

Attuale situazione - Suturatrici lineari taglia e cuci con stelo rotante a 360° 45 mm

LOTTO	Voce	Descrizione Lotto	CODICE PRODOTTO	PREZZO
31	1	Suturatrici lineari taglia e cuci lunghezza linea di sutura da 45 mm	PCEE45A-PSEE45A-PLEE45A	360,00 €
	2	Caricatori per suturatrici lineari monopaziente, taglia e cuci	GST45W	180,00 €
				540,00 €

Meccanismo proposto per consentire l'affiancamento - CODICI PROPOSTI IN AFFIANCAMENTO

Descrizione	CODICE PRODOTTO	PREZZO
Suturatrice lineare taglia e cuci lunghezza di sutura da 45mm, con articolazione a batteria (codice ECH45S) e caricatore a corredo (codice GST45W)	**CKECH45SW**	540,00 €
Suturatrice lineare taglia e cuci lunghezza di sutura da 45mm, con articolazione a batteria (codice ECH45C) e caricatore a corredo (codice GST45W)	**CKECH45CW**	540,00 €

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Suturatrice lineare taglia e cuci lunghezza di sutura da 45mm, con articolazione a batteria (codice ECH45L) e caricatore a corredo (codice GST45W)	**CKECH45LW**	540,00 €

Attuale situazione - Suturatrici lineari taglia e cuci con stelo rotante a 360° 60 mm

LOTTO	Voce	Descrizione Lotto	CODICE PRODOTTO	PREZZO
32	1	Suturatrici lineari taglia e cuci lunghezza linea di sutura da 45 mm	PCEE60A-PSEE60A-PLEE60A	360,00 €
	2	Caricatori per suturatrici lineari monopaziente, taglia e cuci	GST60W	215,00 €
				575,00 €

Meccanismo proposto per consentire l'affiancamento – CODICI PROPOSTI IN AFFIANCAMENTO

Descrizione	CODICE PRODOTTO	PREZZO
Suturatrice lineare taglia e cuci lunghezza di sutura da 60mm, con articolazione a batteria (codice ECH60S) e caricatore a corredo (codice GST60W)	**CKECH60SW**	575,00 €
Suturatrice lineare taglia e cuci lunghezza di sutura da 60mm, con articolazione a batteria (codice ECH60C) e caricatore a corredo (codice GST60W)	**CKECH60CW**	575,00 €
Suturatrice lineare taglia e cuci lunghezza di sutura da 60mm, con articolazione a batteria (codice ECH60L) e caricatore a corredo (codice GST60W)	**CKECH60LW**	575,00 €

I prezzi sono da intendersi I.V.A. esclusa. Si confermano le restanti condizioni generali di fornitura.

Si dichiara che in caso di accettazione della proposta di affiancamento sopra rappresentata e descritta **NON** (i) si introdurrebbero condizioni che, se fossero state contenute nell'offerta originaria della società scrivente, avrebbero consentito l'accettazione di un'offerta diversa da quella inizialmente accettata; (ii) cambierebbe l'equilibrio economico del contratto a favore della società scrivente in modo non previsto nel contratto iniziale; (iii) si estenderebbe l'ambito di applicazione del contratto; (iv) si verificherebbe la lesione di eventuali diritti di fornitura

acquisiti da aziende concorrenti, anche perché si ribadisce che la scrivente è l'unica aggiudicataria per i lotti nn. 31 e 32 della procedura in oggetto.

Pertanto, alla luce di tutto quanto esposto nella presente, la scrivente società chiede a codesto Spett.le Ente la propria disponibilità a volere autorizzare l'affiancamento proposto.

Ci si rende disponibili a fornire ulteriori dettagli o a descrivere in maniera più compiuta il meccanismo di cui sopra anche tramite la partecipazione ad una riunione dedicata con Vs rappresentanti nei tempi e nei modi che eventualmente vorrete rappresentarci.
Si conferma, altresì, che ove intervenisse l'atto dell'accettazione della proposta di affiancamento, la scrivente provvederà ad integrazione relativa a CND e RDM, considerato che, come anticipato, i codici proposti saranno disponibili alla vendita a partire da Settembre 2024.

In attesa di Vs. riscontro si porgono cordiali saluti e si resta a disposizione per ogni ulteriore chiarimento.

Relazione tecnico/scientifica

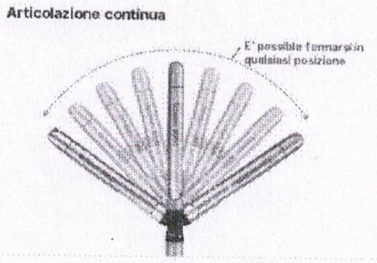
Le esigenze dei chirurghi nelle diverse specialistiche sono in continua evoluzione, parallelamente alla crescente complessità dei pazienti e delle procedure chirurgiche stesse.
L'impegno di Johnson & Johnson Medical è da sempre quello di mettere a disposizione dei clinici strumenti progettati per rispondere efficacemente a queste esigenze mutevoli, adattandosi e migliorando di pari passo con le necessità degli operatori, affinché questi possano svolgere il loro lavoro nelle migliori condizioni possibili e garantire ai pazienti un'assistenza di alta qualità.
Si sottolinea inoltre l'aspetto di sostenibilità, considerato che l'utilizzo della suturatrice meccanica ECHELON™ 3000 con ricariche GST può consentire di eliminare una ricarica per procedura grazie al minore scivolamento tissutale"

L'ultima innovazione tecnologica Johnson & Johnson Medical, **ECHELON™3000** (*Suturatrice lineare, taglia e cuci, con manipolo monouso con batteria per azionamento automatico della lama e articolazione dello stelo, monopaziente, ricaricabile, con stelo articolabile fino a 55°, rotante a 360°, con chiusura manuale della ganasce, con relativi caricatori, per l'anastomosi e la transezione)* rispetto al modello attualmente in uso nelle vostre sale operatorie, **ECHELON POWERED+** (*Suturatrice lineare, taglia e cuci, con manipolo monouso con batteria per azionamento automatico della lama, monopaziente, ricaricabile, con stelo articolabile fino a 45°,*

rotante a 360°, con chiusura manuale della ganasce, con relativi caricatori, per l'anastomosi e la transezione), presenta significativi miglioramenti in termini di accesso, posizionamento e controllo.

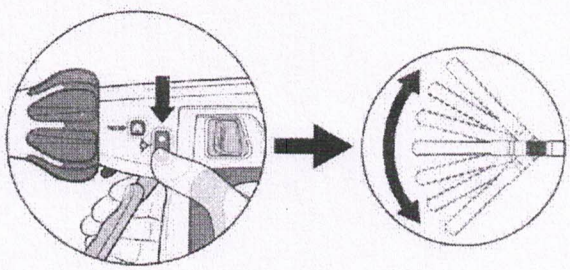
ECHELON™3000 è una suturatrice monouso di ultima generazione perchè, a differenza del modello precedente, possiede un meccanismo di **articolazione a batteria** che consente alla porzione distale dello stelo di ruotare come su un perno **fino a 55°**, per facilitare l'accesso laterale al sito operatorio, consentendo l'uso con una sola mano in tutte le fasi del ciclo di articolazione e azionamento.

L'articolazione della ganascia, a differenza del modello precedente, è progressiva e graduale e può essere interrotta in qualsiasi angolazione.



Il meccanismo di articolazione si attiva a ganasce aperte tramite i pulsanti di controllo posizionati sull'impugnatura dello strumento: **il dispositivo rileva l'orientamento della ganascia rispetto all'impugnatura** per mantenere coerenti i controlli della direzione dell'articolazione.

Per riportare le ganasce nella posizione iniziale (0°) è sufficiente premere il **pulsante di posizione di riposo** (simbolo HOME).

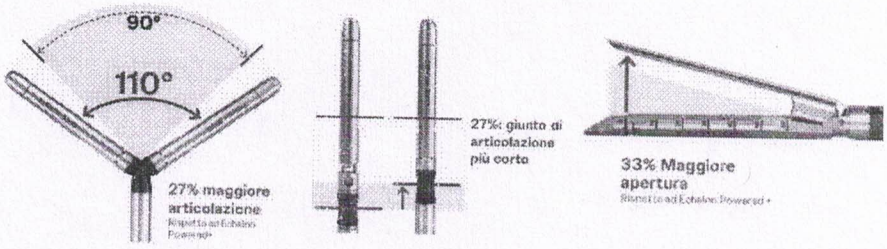


In **ECHELON™3000** tre caratteristiche sono state migliorate rispetto alla ECHELON POWERED+ per consentire al chirurgo un **più semplice e corretto posizionamento dello strumento anche in spazi molto ristretti:**

1- un'ampia apertura delle branche (+33%)

2- un ingombro ridotto grazie allo snodo di articolazione più corto rispetto al modello precedente (-27%)

3- il grado di articolazione bilaterale massimo fino a 55° (+27%)



ECHELON™3000 è una suturatrice particolarmente **intuitiva** perchè i tasti e i grilletti sono progettati per essere facilmente riconoscibili sia nella routine che nelle situazioni di emergenza. Durante l'apertura e la chiusura del dispositivo, l'utilizzatore può avvertire un **riscontro acustico/tattile (click),** inoltre il **motore vibra** per avvertire l'operatore quando si preme il pulsante di controllo dell'articolazione dopo aver raggiunto il suo grado massimo oppure se il giunto è bloccato.

Si conferma che ECHELON™3000 è compatibile con gli stessi caricatori utilizzati con la ECHELON POWERED+, *caricatori con punti in tripla fila sfalsata per ogni linea di sutura per tessuti di vario spessore, compatibili con RNM*, **aggiudicati al lotto 31 voce 2 (misura 45mm) ed al lotto 32 voce 2 (misura 60mm),** codici:

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Codice ricarica	Altezza punto aperto	Altezza punto chiuso	Lunghezza linea di sutura	Colore ricarica	Numero di punti	File di punti	Intervallo di spessori del tessuto
GST45W	2,6 mm	1,0 mm	45 mm	Bianco	70	6	1,0-2,0 mm
GST45B	3,6 mm	1,5 mm	45 mm	Blu	70	6	1,5-2,4 mm
GST45D	3,8 mm	1,8 mm	45 mm	Oro	70	6	1,8-3,0 mm
GST45G	4,1 mm	2,0 mm	45 mm	Verde	70	6	2,0-3,3 mm
GST45T	4,2 mm	2,3 mm	45 mm	Nero	70	6	2,3-4,0 mm
GST60W	2,6 mm	1,0 mm	60 mm	Bianco	88	6	1,0-2,0 mm
GST60B	3,6 mm	1,5 mm	60 mm	Blu	88	6	1,5-2,4 mm
GST60D	3,8 mm	1,8 mm	60 mm	Oro	88	6	1,8-3,0 mm
GST60G	4,1 mm	2,0 mm	60 mm	Verde	88	6	2,0-3,3 mm
GST60T	4,2 mm	2,3 mm	60 mm	Nero	88	6	2,3-4,0 mm

Si allega:

- **Scheda tecnica** Echelon 3000 (Suturatrice lineare, taglia e cuci, con manipolo monouso con batteria per azionamento automatico della lama e articolazione dello stelo, 45mm);
- **Scheda tecnica** Echelon 3000 (Suturatrice lineare, taglia e cuci, con manipolo monouso con batteria per azionamento automatico della lama e articolazione dello stelo, 60mm);
- **Risultati di studi clinici** controllati riportati nella letteratura nazionale e internazionale;
- **certificazioni CE** della classe di appartenenza.

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General Indications

Global Surgeon Opinion on the Impact of Surgical Access When Using Endocutters Across Specialties

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➢ Supplementary Material

ABSTRACT

Background: Despite design enhancements in endocutters, key challenges related to limited surgical access and space can impact stapling and, potentially, surgical outcomes.

Objectives: This study aimed to develop consensus statements outlining the clinical value of precise articulation and greater anatomical access in minimally invasive surgery performed by bariatric, colorectal, and thoracic surgeons.

Methods: Colorectal, bariatric, and thoracic surgeons from Japan, the United States, United Kingdom, and France participated in a 2-round modified Delphi panel. Round 1 included binary, Likert scale–type, multiple-response, and open-ended questions. These were converted to affirmative statements for round 2 if sufficient agreement was reached. Consensus was set at a predefined threshold of at least 90% of panelists across all surgical specialties and regions selecting the same option ("agree" or "disagree") for the affirmative statements.

Results: Of the 49 statements in the round 2 questionnaire, panelists (n = 135) reached consensus that (1) tissue slippage outside stapler jaws can occur due to limited access and space; (2) greater jaw aperture could help to manipulate thick or fragile tissue more easily; (3) articulation of an endocutter is clinically important in laparoscopic surgeries; (4) improved access to hard-to-reach targets and in limited space would improve safety; and (5) an endocutter with improved access through greater articulation would become common use.

Discussion: By understanding user-specific challenges and needs from both specialty- and region-wide perspectives, endoscopic stapling devices can continue to be refined. In this study, improved articulation and greater jaw aperture were the key design features examined. Improved articulation and greater jaw aperture were key stapler design features identified in this study that may mitigate the risk of instrument clashes and intraoperative complications such as anastomotic leaks.

Conclusions: This study gained insights into surgeons' perspective across a variety of specialties and from 3 distinct geographies. Participating surgeons reached consensus that an endocutter with greater jaw aperture and articulation may improve surgical access and has potential to improve surgical outcomes.

INTRODUCTION

There has been widespread adoption of minimally invasive surgery (MIS), which includes laparoscopic and thoracoscopic procedures, both globally and across surgical specialties.[1,2] The International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) estimated that between 99.2% and 99.7% of bariatric surgeries were performed laparoscopically among its 50 contributor countries between 2016 and 2020.[3] Similarly, the use of video-assisted thoracoscopic surgery (VATS) has been increasing worldwide and is the most common approach for lung cancer resection in the United Kingdom (UK).[4] A 2012 analysis estimated that 43% of colorectal procedures in the United States (US) were minimally invasive.[5] MIS can result in faster recovery times, reduced postoperative pain, shortened hospital stays, and improved cosmesis compared with open surgery.[6-8]

Laparoscopic surgical stapling devices facilitate tissue approximation and transection during MIS. Studies comparing stapling devices against suturing found that similar operative outcomes were

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achieved.[10,11] Given the variable dynamic characteristics of tissue, including thickness, compressibility, and elasticity, surgical devices need to complement target tissue properties for optimal stapling.[12] Adequate grip is also key to ensure staple alignment during firing by countering potential tissue slippage.[13] Powered staplers (ie, those for which the staples and the knife blade are driven not by manual force but instead by a battery) provide several benefits compared with non-powered (manual) devices.[14] By reducing the manual force expended by surgeons, their energy can be diverted to maintaining stability and enable more precise and reliable stapling. Relative to manual devices, powered staplers may be associated with improved clinical outcomes and decreased hospital costs.[14-18]

Despite the advancement in endoscopic staplers, key clinical challenges related to limited surgical access and space can impact acceptable stapling and surgical outcomes. Tight spaces in areas like the pelvis and chest cavity can be challenging for surgeons to maneuver and optimally position the stapler.[12] Thicker tissue such as lung parenchyma and stomach can be difficult to capture and are more susceptible to tissue slippage, therefore potentially requiring additional manipulation.[12,19] The ability to place the jaws of the stapler precisely where the surgeon intends is key to enabling surgeons to successfully carry out procedures.

We sought to understand the potential impact and unmet need, from the surgeons' perspective, of limited surgical access and space for stapling, which to our knowledge have not been documented. The objective of this study was to develop consensus statements outlining the clinical value of precise articulation and greater anatomical access in MIS procedures performed by bariatric, colorectal, and thoracic surgeons.

METHODS

The modified Delphi method is a widely used, systematic, and robust methodology to gather expert consensus using several rounds of iterative questionnaires.[20,21] Participants are provided with a series of questions to answer anonymously, eliminating any influence of group pressure on individuals' responses. The Delphi panel process enables users to share their experiences, needs, and challenges in an open-ended format, such that the impact of stapling device design can be evaluated and potentially utilized to facilitate design improvements to address any unmet need(s).

Delphi Panelists

Eligible panelists from Japan, the US, the UK, and France were board-certified colorectal, bariatric, or thoracic full-time practicing surgeons who perform on average at least 10 relevant surgeries per month. In addition, panelists must have performed at least 10 procedures per month using endocutters (endoscopic linear stapling device). Panelists were invited via email and asked to respond in the affirmative if they wished to participate in the Delphi panel. Complete eligibility criteria are available in **Supplementary Table S1**.

Study Procedures and Evaluations

This study used a modified Delphi method, which prespecified that 2 questionnaire rounds would be conducted and delivered through a web-based platform. The first round included a screening questionnaire to ensure all potential panelists met the eligibility criteria. Questions in round 1 were developed from assumptions of the unmet need, based on current literature, and the authors' own subject matter expertise and experience. A detailed list of the round 1 and 2 survey questions is available in the **Supplementary Material**.

The question types posed in the survey were open-ended, ranking, multiple-response, binary (yes/no and agree/disagree) and Likert scale. Panelists were able to provide a free-text comment to contextualize their response and/or make suggestions for round 2.

Responses to the Likert scale questions were given on a 5-point scale where 5 = extremely clinically important, 4 = very clinically important, 3 = somewhat clinically important, 2 = not very clinically important, and 1 = not at all clinically important. Responses from round 1 facilitated the development of binary-response questions for round 2. Statements from round 1 that had at least 70% agreement among respondents in all counties or specialties and/or were ranked in the top 3 most common responses (for multiple-response questions or ranking questions) were further explored in round 2, where respondents had the option to agree or disagree with the most common responses presented as affirmative statements. All responses provided during the Delphi rounds were anonymized. No patients were involved in the study, and therefore ethical approval was not required. Respondents and study sponsors were blinded to each other.

Statistical Analysis

Results were exported directly from the online survey and analyzed in Microsoft Excel. Consensus was set at a predefined threshold of at least 90% of panelists across every surgical specialty (ie, bariatric, thoracic, colorectal) and region (ie, US, Europe, and Japan) selecting the same option (agree or disagree) for the affirmative statements posed in round 2. Agreement rather than consensus was established by at least 90% of panelists within a subgroup (ie, either by specialty or region) selecting the same option (either agree or disagree). Responses from surgeons in France and UK were grouped together under the broader category of Europe. The predefined ≥90% threshold was chosen to increase fidelity and ensure that consensus could be achieved within 2 rounds, as is conventional in a modified Delphi study. It has been noted that the definition of consensus used in published Delphi studies is discrepant, with thresholds varying widely from 50% to 97%.[21]

RESULTS

Round 1 of the Delphi panel was conducted from March 23, 2022, to April 29, 2022. Round 2 was open from August 12, 2022, to September 22, 2022. In total, 177 eligible panelists completed round 1, with a total of 135 panelists having completed both round 1 and 2 questionnaires (**Figure 1**).

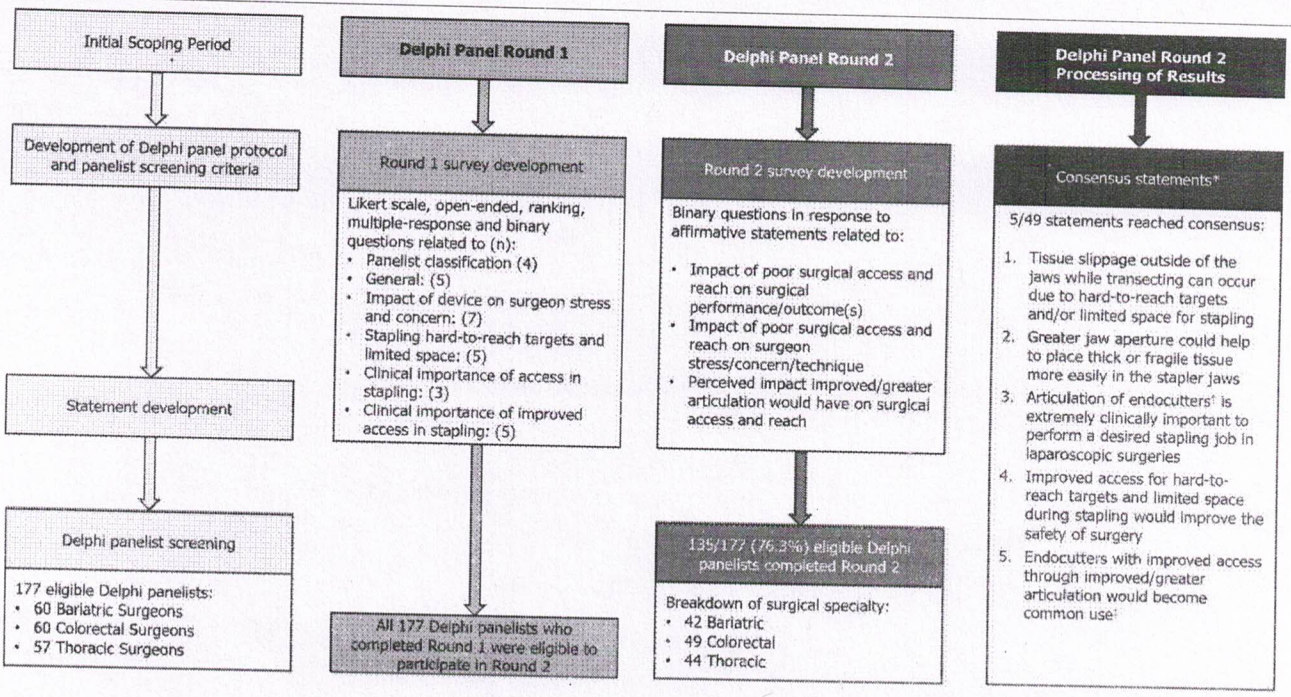
Of the 135 panelists that completed round 2, 31.1% were bariatric surgeons, 32.6% thoracic surgeons, and the remaining 36.3% colorectal surgeons. The majority of respondents were male (94.1%) and performed the majority of surgeries laparoscopically (for bariatric and colorectal surgeons, 53.7%) or as VATS (for thoracic surgeons, 50.0%). A description of panelists who completed rounds 1 and 2 is presented in **Table 1**.

The affirmative statements presented in round 2 were divided into 3 main areas: impact of limited surgical access and space on surgical performance/outcome(s) (**Table 2**), impact of limited surgical access and space on surgeon stress/concern/technique (**Table 3**), and perceived impact of improved/greater articulation in stapling on surgical access (**Table 4**). Overall, 49 statements were developed from responses provided in round 1. Of the 49 statements in the round 2 questionnaire, 5 statements reached consensus: 1 relating to the impact of limited surgical access and space on surgical performance/outcome(s) (consensus statement 1) and 4 on the perceived impact of improved/greater articulation in stapling on surgical access (consensus statements 2-5):

1. Tissue slippage outside of the jaws while transecting can occur due to hard-to-reach targets and/or limited space for stapling.

2. Greater jaw aperture feature could help to place thick or fragile tissue more easily in the stapler jaws.
3. Articulation of endocutters is extremely clinically important to perform a desired stapling job in laparoscopic surgeries.
4. Improved access for hard-to-reach targets and limited space during stapling would improve safety of surgery.
5. Endocutters with improved access through improved/greater articulation would become common use.[22]

Figure 1. Delphi Panel Study Flowchart



*Consensus was set at a predefined threshold of at least 90% of panelists across every surgical specialty (ie, bariatric, thoracic, colorectal) and region (ie, US, Europe, and Japan) selecting the same option (either "agree" or "disagree") for the affirmative statements posed in round 2.

†"Endoscopic linear stapler/stapling device" was used in the Delphi panel questionnaire to refer to "endocutters," and these two terms have been used interchangeably.

‡"Standard of care" rather than "common use" was presented in the Delphi panel questionnaire.

Table 1. Delphi Panelist Characteristics of Those Who Completed Rounds 1 and 2

Characteristic	Value, n (%)
Panelists	135
Male	127 (94.1)
Female	8 (5.9)
Bariatric surgeons	42 (31.1)
Average No. (proportion) of laparoscopic procedures per surgeon/mo	20 (51.0)
Colorectal surgeons	49 (36.3)
Average No. (proportion) of laparoscopic procedures per surgeon/mo	28 (55.9)
Thoracic surgeons	44 (32.6)
Average No. (proportion) of VATs per surgeon/mo	14 (50.0)
Practice setting	
Teaching hospital (public or private)	73 (54.1)
Non-teaching hospital	55 (40.7)
Others	7 (5.2)
Regions represented	
Europe[a]	40 (29.6)
France	19 (14.1)
UK	21 (15.6)
Japan	55 (40.7)
US	40 (29.6)

Abbreviation: VATS, video-assisted thoracoscopic surgery.

[a]Percentage calculated using the number of panelists from France and UK (n = 40) and not summing individual percentage values.

Impact of Limited Surgical Access and Space on Surgical Performance/Outcome(s)

Full results for statements related to the impact of limited surgical access and space on surgical performance/outcome(s) are shown in **Table 2.** Consensus was reached that hard-to-reach targets and/or limited space for stapling can result in tissue slippage outside of jaws while transecting (consensus statement 1), and 4 of 6 subgroups were in agreement that this would also result in increased tension on the structure or tissue the surgeon is firing on; surgeons in the US and bariatric surgeons reached 88% agreement.

Specialty-specific differences. Colorectal surgeons reached agreement on all 6 statements relating to the impact of limited surgical access and space on stapling, while thoracic and bariatric surgeons reached agreement on 2 and 1 of these statements, respectively (**Table 2**).

Similarly, colorectal surgeons reached agreement on 4 out of the 5 statements related to complications of limited surgical access and space when using endocutters to create staple lines (**Table 2**). Neither bariatric or thoracic surgeons reached agreement on any of the 5 statements. Across all 11 statements, the minimum level of agreement across surgical specialty was 73%.

Region-specific differences. There was most agreement among European surgeons on the impact of limited surgical access and space on stapling (agreement reached on 5 of 6 statements). Surgeons in both the US and Japan reached agreement on 2 of these 6 statements (**Table 2**).

Generally, statements on complications reached less agreement than statements relating to impact of limited surgical access and space. Surgeons in both the US and Europe reached agreement on 2 of 5 statements on the complications, but surgeons in Japan did not reach agreement on any of the statements (**Table 2**). Across all 11 statements, the minimum level of agreement across regions was 78%.

Impact of Limited Surgical Access and Space on Surgeon Stress/Concern/Technique

Full results of agreement on statements related to the impact of limited surgical access and space on surgeon stress/concern/technique can be found in **Table 3.**

Although none of the statements reached consensus, all surgeons with the exception of those practicing in Japan (85% agreement) and bariatric surgeons (88% agreement) reached agreement that "angulation change/change angle of approach/twist/rotate/move around" was a type of compensating behavior used to adjust for hard-to-reach targets and limited space. In addition, all surgeons except for bariatric surgeons (88% agreement) and those practicing in Japan (89% agreement) reached agreement that having a "visualization change/look from different perspectives" was another form of compensating behavior (**Table 3**).

None of the subgroups reached agreement on whether they experienced stress or were concerned that "hard-to-reach areas [would] compromise their surgical training during a procedure" (range of agreement, 30%-44%). The panelists, within any subgroup, were also not in agreement that they experienced "physical distress or discomfort when facing a situation of a hard-to-reach area [that required a] difficult approach to address a bleeding vessel or pedicle" (range of agreement, 28%-47%).

Table 2. Survey Results from Round 2 on the Impact of Limited Surgical Access and Space on Surgical Performance/Outcome(s)

Statement	Consensus Agreement[a]	Percentage Agreement						
		Total	Region			Specialty		
			US	Europe	Japan	Bariatric	Colorectal	Thoracic
Impact of limited surgical access and space when using endocutters[b]								
Tissue slippage outside of the jaws while transecting	Consensus agreement reached	92%	90%	95%	91%	95%	90%	91%
Increased tension on the structure or tissue surgeon is firing on	Agreement reached in 4/6 subgroups	92%	88%	98%	91%	88%	94%	93%
Needing extra reloads to compensate for tissue slipping outside the jaws	Agreement reached in 2/6 subgroups	88%	95%	88%	84%	83%	96%	84%
Tearing of fragile tissue away from the staple line	Agreement reached in 2/6 subgroups	88%	85%	90%	89%	86%	92%	86%
Tearing of fragile tissue along the staple line	Agreement reached in 2/6 subgroups	86%	78%	95%	85%	86%	94%	77%
Poor staple line quality	Agreement reached in 2/6 subgroups	84%	78%	90%	84%	86%	92%	73%
Complications of limited surgical access and space when using endocutters to create staple lines								
Less surgical margin than expected	Agreement reached in 2/6 subgroups	89%	93%	88%	87%	86%	94%	86%
Tissue trauma that requires further repair	Agreement reached in 3/6 subgroups	89%	95%	95%	80%	88%	92%	86%
Staple line oozing/bleeding controllable with clips, suture, or fibrin glue	No agreement reached in any subgroup	85%	83%	83%	89%	81%	88%	83%
Tearing of fragile tissue away from the staple line	Agreement reached in 1/6 subgroups	84%	78%	85%	87%	86%	90%	75%
Tearing of fragile tissue along the staple line	Agreement reached in 2/6 subgroups	86%	80%	90%	87%	86%	92%	80%

Shaded values indicate agreement.

[a]Consensus was set at a pre-defined threshold of ≥90% of panelists across every surgical specialty (ie, bariatric, thoracic, colorectal) and region (ie, US, Europe, and Japan) selecting the same option (either "agree" or "disagree") for the affirmative statements posed in round 2.

[b]"Endoscopic linear stapler/stapling device" was used in the Delphi panel questionnaire to refer to "endocutters," and these two terms have been used interchangeably.

Table 3. Survey Results from Round 2 on the Impact of Limited Surgical Access and Space on Surgeon Stress/Concern/Technique

Statement	Consensus Agreement[a]	Percentage Agreement						
		Total	Region			Specialty		
			US	Europe	Japan	Bariatric	Colorectal	Thoracic
Type of compensating behavior adopted to and/or adjust for in hard-to-reach targets and limited space								
Angulation change/change angle of approach/twist/rotate/move around	Agreement reached in 4/6 subgroups	93%	95%	100%	85%	88%	98%	91%
Visualization change/look from different perspectives	Agreement reached in 4/6 subgroups	90%	90%	93%	89%	88%	92%	91%
Additional/further dissection	Agreement reached in 2/6 subgroups	87%	90%	85%	87%	88%	90%	84%
Adding or using another port	Agreement reached in 1/6 subgroups	84%	78%	75%	95%	88%	86%	77%
Delicate/slower/more fine handling of stapler	Agreement reached in 2/6 subgroups	84%	78%	80%	91%	93%	80%	80%
Suturing over trouble spots	No agreement reached in any subgroup	81%	80%	73%	87%	83%	82%	77%
The use of additional trocars/switch or change trocars	Agreement reached in 1/6 subgroups	79%	70%	70%	91%	83%	80%	73%
The use of different staples/different staple loads	Agreement reached in 1/6 subgroups	76%	63%	78%	85%	64%	90%	73%
The use of multiple fires/double stapling	No agreement reached in any subgroup	76%	73%	65%	87%	76%	82%	70%
The use of staple line reinforcing	No agreement reached in any subgroup	71%	65%	65%	80%	74%	78%	61%
Stress or concern experienced by surgeons								
Anticipate that the surgeon would have less stress or concern if the surgeon was using endocutters[b] with improved articulation in surgery	Agreement reached in 4/6 subgroups	93%	100%	80%	98%	93%	98%	89%
Anticipate that the surgeon would have less stress or concern if the surgeon was training a fellow or resident during surgery with endocutters with improved articulation	Agreement reached in only 1/6 subgroups	79%	73%	68%	91%	74%	88%	73%
Experience stress or concern when the surgeon has a less accessible approach to a vessel or pedicle that may increase the chance of harm/injury to a vessel or pedicle	Agreement reached in 3/6 subgroups	84%	93%	65%	93%	90%	78%	86%
Experience stress or concern that a hard-to-reach bleeding pedicle or vessel may lead to a higher probability of surgical complication	No agreement reached in any subgroup	81%	85%	80%	80%	79%	86%	80%
Experience stress or concern when the surgeon must adjust to the limits of the device	No agreement reached in any subgroup	79%	83%	60%	89%	88%	80%	68%
Experience stress or concern when the surgeon needs to convert from laparoscopic to open surgery due to failure of endocutters to secure pedicle or blood vessel	No agreement reached in any subgroup	79%	78%	68%	87%	86%	73%	77%
Do not experience stress or concern that a hard-to-reach area may compromise my surgical training during a procedure	No agreement reached in any subgroup	39%	30%	40%	44%	36%	41%	39%
Do not experience physical distress or discomfort when facing a situation of a hard-to-reach area with difficult approach to address a bleeding vessel or pedicle	No agreement reached in any subgroup	36%	28%	30%	47%	43%	31%	36%

Shaded values indicate agreement.

[a]Consensus was set at a predefined threshold of at least 90% of panelists across every surgical specialty (ie, bariatric, thoracic, colorectal) and region (ie, US, Europe, and Japan) selecting the same option (either "agree" or "disagree") for the affirmative statements posed in round 2.

[b]"Endoscopic lineal stapler/stapling device" was used in the Delphi panel questionnaire to refer to "endocutters," and these 2 terms have been used interchangeably.

Table 4. Survey Results from Round 2 on Perceived Impact Improved/Greater Articulation in Stapling Would Have on Surgical Access

Statement	Consensus Agreement[a]	Percentage Agreement						
		Total	Regions			Specialty		
			US	Europe	Japan	Bariatric	Colorectal	Thoracic
Impact of devices with improved/greater articulation in stapling								
Difficult angles become less stressful	No agreement reached in any subgroup	79%	80%	70%	85%	79%	86%	73%
Space restrictions become less stressful	No agreement reached in any subgroup	76%	78%	60%	85%	79%	78%	70%
Inability of the device to access target anatomy becomes less stressful	No agreement reached in any subgroup	61%	75%	58%	53%	57%	61%	64%
Decreased visibility to access target anatomy becomes less stressful	No agreement reached in any subgroup	61%	75%	55%	55%	55%	67%	59%
Features that facilitate reaching difficult-to-access targets								
Greater jaw aperture feature could help to place thick or fragile tissue more easily in the stapler jaws	Consensus agreement reached	93%	95%	95%	91%	90%	90%	100%
Greater articulation span feature could help the surgeon reach difficult to access targets	Agreement reached in 3/6 subgroups	90%	93%	85%	91%	86%	94%	89%
Greater jaw aperture feature could help the surgeon reach difficult to access targets	Agreement reached in 2/6 subgroups	87%	80%	85%	95%	83%	90%	89%
Easy to use, one-handed operation feature could help the surgeon reach difficult to access targets	Agreement reached in 1/6 subgroups	84%	83%	88%	84%	74%	92%	86%
Important concerns/considerations for laparoscopic surgeons								
When performing a desired stapling job, the articulation of endocutters[b] is extremely clinically important for laparoscopic surgeries	Consensus agreement reached	93%	93%	90%	96%	95%	92%	93%
Surgeons perceive that improved access through improved/greater articulation in stapling would have a positive clinical effect on surgical outcomes	Agreement reached in 2/6 subgroups	87%	98%	83%	84%	79%	94%	89%
Surgeons have less stress or concern when an assistant is firing endocutters with improved articulation during a robot-assisted surgery procedure, where there may be hard to reach targets and limited space increasing the difficulty of firing	Agreement reached in only 1/6 subgroups	77%	73%	60%	93%	74%	78%	80%
Surgeons spend 10% extra time in pre-operative assessment for patients with predictable compromised surgical access (hard-to-reach targets and limited space)	No agreement reached in any subgroup	65%	53%	60%	78%	67%	67%	61%
Surgeons do not spend extra time in pre-operative assessment for a procedure with predictable compromised surgical access (hard-to-reach targets and limited space)	No agreement reached in any subgroup	44%	35%	38%	55%	40%	47%	43%

Table 4. Survey Results from Round 2 on Perceived Impact Improved/Greater Articulation in Stapling Would Have on Surgical Access, *cont'd*

Statement	Consensus Agreementa	Percentage Agreement						
		Total	Regions			Specialty		
			US	Europe	Japan	Bariatric	Colorectal	Thoracic
Impact of devices with improved access for hard-to-reach targets and limited space in stapling								
Improve safety of surgery	Consensus agreement reached	97%	98%	98%	96%	95%	98%	98%
Reduce unintentional tissue/structure damage	Agreement reached in 5/6 subgroups	93%	93%	98%	91%	83%	96%	100%
Reduce tension on the tissue/structure the surgeon was firing on	Agreement reached in 5/6 subgroups	93%	93%	93%	95%	98%	88%	95%
Reduce tearing of fragile tissue away from the staple line	Agreement reached in 3/6 subgroups	91%	88%	88%	96%	93%	88%	93%
Reduce surgical stress	Agreement reached in 4/6 subgroups	89%	90%	83%	93%	83%	92%	91%
Impact of devices with improved access through improved/greater articulation in stapling								
Endocutters with improved access through improved/greater articulation in stapling would become common use[c]	Consensus agreement reached	96%	93%	95%	100%	95%	98%	95%
If an endocutter device gave improved access through improved/greater articulation in stapling compared to currently available choices, the surgeons would use in most of their procedures	Agreement reached in 5/6 subgroups	92%	95%	98%	85%	95%	92%	89%

Shaded values indicate agreement.

[a]Consensus was set at a pre-defined threshold of ≥90% of panelists across every surgical specialty (ie, bariatric, thoracic, colorectal) and region (ie, US, Europe, and Japan) selecting the same option (either "agree" or "disagree") for the affirmative statements posed in round 2.

[b]"Endoscopic linear stapler/stapling device" was used in the Delphi panel questionnaire to refer to "endocutters," and these two terms have been used interchangeably.

[c]"Standard of care" rather than "common use" was presented in the Delphi panel questionnaire.

Perceived Impact of Improved/Greater Articulation in Stapling on Surgical Access

Full results for statements related to the perceived impact of improved/greater articulation in stapling on surgical access are shown in **Table 4**. It should be noted that panelists' responses were independent of observations made in scientific studies and represented their opinion.

Consensus opinion was reached that "greater jaw aperture feature could help to place thick or fragile tissues more easily in the stapler jaws" (consensus statement 2). Consensus was reached among the panelists that "the articulation of endocutters is extremely clinically important" to "[perform] a desired stapling job [in laparoscopic surgeries]" (consensus statement 3).

Panelists were in consensus that "improved access for such hard-to-reach targets and limited space during stapling would improve the safety of the surgery" (consensus statement 4) and "Endocutters with improved access through improved/greater articulation in stapling would become common use" (consensus statement 5).

Similar to the statements related to surgeon stress or concern, none of the subgroups reached agreement that the "inability of the device to access target anatomy" (range of agreement, 53%-75%) and "decreased visibility to access target anatomy becomes less stressful" (range of agreement, 55%-75%) if endocutters with improved/greater articulation was used.

Additionally, none of the subgroups were in agreement that 10% extra time [was spent on] pre-operative assessments for patients or procedures with predictable compromised surgical access (hard-to-reach targets and limited space) (range of agreement, 53%-78%).

Reduced unintentional tissue/structure damage (range of agreement, 83%-100%), reduced tension on the tissue/structure fired on (range of agreement, 88%-98%), reduced tearing of fragile tissue away from the staple line (range of agreement, 88%-96%), and reduced surgical stress (range of agreement, 83%-93%) also did not reach consensus.

Specialty-specific differences. It was agreed among colorectal and thoracic surgeons that improved access for hard-to-reach targets and limited space in stapling would reduce unintentional tissue/structure damage and would reduce surgical stress with the bariatric surgeon subgroup not reaching agreement on these statements (83% agreement for both statements).

Colorectal surgeons reached agreement on all 4 statements related to features that facilitate reaching difficult-to-access targets (**Table 4**). They agreed that having a greater jaw aperture, articulation span, and easy-to-use, one-handed operation would help surgeons to place thick or fragile tissues more easily in stapler jaws and improve access to targets.

However, colorectal surgeons were the only specialists who did not reach agreement that devices with improved access for hard-to-reach targets and limited space in stapling would reduce tension on the structure or tissue being fired on (88% agreement) and reduce tearing of fragile tissue away from the staple line (88% agreement). Across all 20 statements, the minimum level of agreement across surgical specialties was 35%.

Region-specific differences. Surgeons in Japan reached agreement on 3 out of 4 statements related to features that facilitate reaching difficult-to-access targets (**Table 4**). They were also in agreement that greater jaw aperture and articulation span would facilitate thick or fragile tissue placement in stapler jaws and improve access to targets.

However, there was least agreement (85% agreement) among panelists in Japan on whether surgeons would use endocutters, which gave improved access through greater articulation in place of the existing stapler choices. In contrast, surgeons in the US and Europe reached agreement on using endocutters with greater articulation (95% and 98% agreement, respectively).

Generally, there was agreement on statements related to the impact of devices that improved surgical access and reach across every region, with surgeons in Japan agreeing with all 5 statements, followed by the US reaching agreement on 4 out of 5 statements (**Table 4**). Surgeons in Europe agreed with only 3 out of 5 statements and did not reach agreement that devices with improved access reduced tearing of fragile tissue away from the staple line and reduced surgical stress (88% and 83% agreement, respectively). Across all 20 statements, the minimum level of agreement across regions was 35% (**Table 4**).

DISCUSSION

Hard-to-reach targets and limited space for stapling present challenges for surgeons. While design improvements to endocutters seek to alleviate these constraints, the potential impact and unmet needs from surgeons' perspective of limited surgical access and space on stapling have not yet been fully elucidated. This modified Delphi panel gained insights into surgeons' perspective across a variety of specialties and from 3 distinct geographies.

Among the presented statements, consensus was achieved in areas pertaining to the impact of limited surgical access and space on surgical performance/outcome and the perceived impact of improved/greater articulation in stapling on surgical access. Specifically, panelists were in consensus about the clinical importance of articulation of endocutters (consensus statement 3). Given the restricted space in body cavities such as the pelvis and thorax, minimally invasive procedures in these areas are challenging and require the surgeon to navigate tight spaces.[12,23] In this study, the panelists agreed that articulation of stapling devices is an important feature to achieve optimal stapling during laparoscopic surgery. Furthermore, the panelists' consensus opinion was that improved access for hard-to-reach targets and limited space during stapling would improve safety of surgery (consensus statement 4). While comparative studies are limited, a wider range of articulation can permit difficult stapling angles and enables surgeons to access tissue in tight spaces, potentially mitigating the risk of instrument clashes.[24]

In thoracic surgeries, tissue slippage can also lead to complications, including but not limited to intraoperative bleeding.[18] Similarly, in bariatric surgery, thick gastric tissue is susceptible to tissue slippage during stapling and may negatively impact staple line integrity.[13] While the Delphi study panelists were in consensus that tissue slippage can occur in constricted anatomical spaces (consensus statement 1), tissue slippage can also be a challenge during bariatric surgeries which are performed in relatively less constricted spaces compared with the pelvic or thoracic cavity.[13]

Participants were also in consensus that greater jaw aperture would improve handling of thick or fragile tissues (consensus statement 2). A 2009 study by Gossot et al[19] examined the occurrence of adverse events related to endoscopic stapler usage in VATS and drew similar conclusions. Possible underlying causes of surgical complications in VATS include the limited ability of staplers with a narrow jaw aperture in handling tissue, indicating how improvements to stapler design may improve outcomes in MIS.

By understanding user-specific challenges and needs from both specialty- and region-wide perspectives, endoscopic stapling devices can continue to be refined. In this study, improved articulation and greater jaw aperture were the key design features examined. In colorectal surgery, the tight space in the pelvis makes it technically challenging to perform anastomosis.[12] Narrow confines of the pelvic cavity limits space for insertion of stapling devices, affecting tissue traction and optimal cutting angles. This may necessitate multiple linear staple firings

which have been suggested to increase the risk of anastomotic leak.[25,26] A stapler with improved articulation could potentially mitigate such risk, and offers insight as to why the colorectal surgeon panelists were largely in agreement on the features that could facilitate reaching difficult-to-access targets.

Bariatric panelists had a relatively lower level of agreement on the impact of limited surgical access and space on surgical performance/outcome(s) (minimum level of agreement remained at 81%), suggesting that they perhaps have greater ease in compensating for insufficient articulation and jaw aperture of endocutters compared with colorectal surgeons. It is possible that due to the relatively less constricted abdominal cavity, the optimal staple angle can be achieved with less articulation than required in a more constricted anatomical space.

From the perspective of thoracic surgeons, a 2018 study by Shimizu et al[27] proposed that twisting and lifting actions exert stress on pulmonary vessels and decrease vessel stump endurance upon sealing. Such twisting and lifting actions constitute compensating behaviors performed by surgeons to reach hard-to-access targets with limited space for stapling, as surveyed in this Delphi panel study. Improved stapler articulation may limit the need for these compensating actions, increasing the likelihood of favorable surgical outcomes.

The survey responses gathered in this modified Delphi panel represented surgeon opinions gathered from a diverse range of regions and surgical specialties from a relatively large number of panelists. Although there was an expected drop-off in participation between survey rounds, this study was still able to facilitate the coverage of specialty-specific nuances, highlighting challenges that are more commonly faced in specific types of surgeries. Similarly, the Delphi study design enabled the gathering of country-specific challenges faced by surgeons and consolidation of a holistic view of the unmet needs in laparoscopic surgeries. Key among them is articulation of endocutters, as exemplified by the consensus opinion that endocutters with improved access through improved/greater articulation would become common use (consensus statement 5).

Nonetheless, this study does have limitations, attributed to the nature of Delphi studies. Consensus regarding the benefits of greater articulation and jaw aperture of endoscopic staplers was gathered by posing statements of a hypothetical nature. The study was also limited in gathering consensus on subjective behavioral traits such as stress and concern, as reflected by the lack of consensus in statements related to this area. The framing of these statements related to such subjective areas could be improved upon in future work to elicit a clearer response. Results were based on survey responses rather than real-world outcomes and should supplement evidence-based guidance, not replace it. In addition, more than 90% of the panelists were male, and therefore female surgeons are underrepresented in the current Delphi study.28 However, this study identified unmet needs with stapling devices during MIS on a region- and specialty-wide level from the perspective of the surgeon. Insights gathered from this study may lead to stapling device design improvements and potentially facilitate optimal surgical stapling in constricted anatomical spaces.

CONCLUSION

While there is a growing body of literature on endoscopic stapling and studies investigating the usefulness of new stapler features, such studies tend to be conducted within specific countries and specialties. This Delphi panel provided a broader view of the unmet needs across specialties and countries from the perspective of the surgeon. Ultimately, the consensus opinion among participating surgeons was that endocutters with greater jaw aperture and articulation may improve surgical access and that such a device would become common use.

Author Contributions: Substantial contributions to this study are as follows: conception and design: M.G., N.J., W.P., and S.R.; analysis and interpretation of the data: M.G., N.J., W.P., and S.R.; drafting the article or revising it critically for important intellectual content: M.G., N.J., W.P., and S.R.; and final approval of the version of the article to be published: M.G., N.J., W.P., and S.R.

Disclosures: M.G., W.P., and S.R. are employees of Johnson & Johnson. N.J. was an employee of Johnson & Johnson at the time of the study.

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English

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EU DECLARATION OF CONFORMITY

Manufacturer's Name	Ethicon Endo-Surgery, LLC
Manufacturer's Address	475 Calle C Guaynabo, Puerto Rico 00969 USA
Manufacturer's Single Registration Number (SRN)	US-MF-000013107
Authorized Representative's Name and Address	Johnson & Johnson Medical GmbH Robert-Koch-Strasse 1 22851 Norderstedt Germany
Authorized Representative's Single Registration Number (SRN)	DE-AR-000007712
Notified Body Name	TÜV SÜD Product Service GmbH
Notified Body Identification Number	0123
Technical Documentation Number	501010007
Product and Trade Name(s)	Refer to Attachment 1
Product Code(s)/Product Range and Description	Refer to Attachment 1
Intended Purpose	Refer to Attachment 1
Classification	Refer to Attachment 1
EMDN Code	Refer to Attachment 1
Basic UDI-DI value	Refer to Attachment 1
RoHS	We, Ethicon Endo-Surgery, LLC, hereby declare the above listed Medical Devices complies with the European Restriction of Hazardous Substances (RoHS) Directive (2011/65/EU) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
Machinery Directive	We, Ethicon Endo-Surgery, LLC, hereby declare the above listed Medical Devices complies with the Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery.

This EU Declaration of Conformity is issued under the sole responsibility of the Manufacturer.

We, Ethicon Endo-Surgery, LLC, hereby declare the above listed Medical Device(s) complies with Medical Device Regulation (EU) 2017/745.

This declaration is made on the basis of:
EU Technical Documentation Assessment Certificate Number G70 057666 0073 (PLM# 501918015), issued by the Notified Body stated above, in accordance with Annex IX, Chapter II of the Medical Device Regulation (EU) 2017/745.

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Name/Title	Kimberly Shoemaker, Senior Director of Regulatory Affairs		
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Note: The English DoC is considered the "EN Master DoC". The dated signature present in the "EN Master DoC" will represent the date of validity for any translated DoCs.

ATTACHMENT 1

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EU DECLARATION OF CONFORMITY

Manufacturer's Name	Ethicon Endo-Surgery, LLC
Technical Documentation Number	501010007

Product Code	Product and Trade Names(s)	Intended Purpose	Classification	EMDN Code	Basic UDI-DI value
ECH45C	ECHELON™ 3000 45 mm Compact Stapler	The ECHELON™ 3000 and ECHELON ENDOPATH™ families of staplers and reloads are intended for transection, resection, and/or creation of anastomoses.	Class III (Annex VIII, Rule 6)	H020301050199	0705036a0007473
ECH45S	ECHELON™ 3000 45 mm Standard Stapler		Class III (Annex VIII, Rule 6)	H020301050199	0705036a0007473
ECH45L	ECHELON™ 3000 45 mm Long Stapler		Class III (Annex VIII, Rule 6)	H020301050199	0705036a0007473
ECH60C	ECHELON™ 3000 60 mm Compact Stapler		Class III (Annex VIII, Rule 6)	H020301050199	0705036a0007473
ECH60S	ECHELON™ 3000 60 mm Standard Stapler		Class III (Annex VIII, Rule 6)	H020301050199	0705036a0007473
ECH60L	ECHELON™ 3000 60 mm Long Stapler		Class III (Annex VIII, Rule 6)	H020301050199	0705036a0007473

Declaration of Conformity - ECHELON 3000 Stapler Rev C

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ORIGINAL RESEARCH

Improving Performance and Access to Difficult-to-Reach Anatomy with a Powered Articulating Stapler

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Background: Modern surgical staplers should provide precise placement and transection, especially in tight spaces and on thick tissue. Ideally, a stapler would move to accommodate variations in the tissue and anatomy instead of having to move the tissue around to fit the stapler. This study was undertaken to evaluate the performance characteristics of the new Echelon 3000 Stapler (ECH3). Use of the ECH3 was compared to another marketed stapler, including tests for access, seal strength, staple formation in thick tissue, and end effector stability.

Methods: Pelvic anatomy measurements were used to construct a virtual model of a Low Anterior Resection (LAR). Monte Carlo simulations were performed on the staplers to compare the probability of completing a transection with one or two firings. Using water infusion of stapled porcine ileum, pressure at first leak and percentage of leaks at critical pressures were measured. Rate of malformed staples was measured in thick tissue. End effector stability while firing and under moderate pressure were compared between staplers. After use, surgeons were surveyed on the functionality of the device.

Results: ECH3 had a markedly higher probability of completing an LAR transection in one or two firings than the comparator stapler. Median initial leak pressure of stapled ileum was significantly higher, and rate of leaks was lower at 40 and 50 mmHg. ECH3 had fewer malformed staples for both 3.3- and 4.0-mm thick tissue. The end effector exhibited less angular movement during firing, and less deflection under a moderate load. Surgeons agreed the ECH3 provided precise placement and easy one-handed operation.

Conclusion: The Echelon 3000 Stapler demonstrated improved access capability, tighter seals, fewer malformed staples, and greater end effector stability. These advantages were recognized by surgeons who evaluated the use of the device preclinically.

Keywords: stapler, access, pelvis, maneuverability, powered articulation

Introduction

Increasingly complex procedures leave very little margin for error when using surgical staplers. Technological advances in surgical staplers have provided surgeons improved utility and functionality to enhance surgical care. Desired features of a surgical stapler include the ability to have precise placement and transection, especially in tight spaces and on thick tissue. Ideally, a stapler would move to accommodate variations in the tissue instead of having to move the tissue around to fit the stapler.

Fragile and variable levels of tissue thickness in patients can lead to tissue movement between the jaws of a stapler affecting the results of an intended transection. The tissue movement during firing may disrupt the integrity of the staple line, which can result in exposed tissue layers, malformed formed staples, and need for extra firings. Staple line failure can result in significant postoperative morbidity in the case of anastomotic leak or staple line bleeding. The most common problems associated with staplers, include failure to fire, malformed staples and handle lockup, that can lead to complications such as bleeding or leaks.[1]

The development of articulated staplers to facilitate the division of vessels and tissue deep in transection planes such as the pelvis has been useful.[2,3] Maneuverability of surgical staplers into a precise position has been shown to allow

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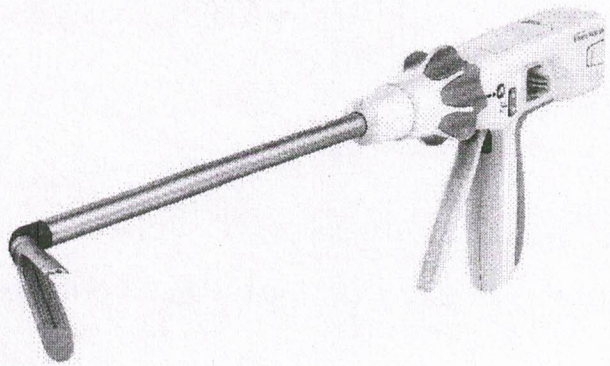

Figure 1 The Echelon 3000 Stapler.

a surgeon to reduce operation time due to making fine stapling position adjustments without having to remove the stapler.[4]

Another important feature to a surgical stapler is how wide the jaw opens. The jaw aperture needs to be wide enough to grasp or hold thick tissue. If the jaw on a stapler does not open wide enough, the stapler is unable to divide and staple thick tissue, potentially increasing the risk for inadequate staple formation with stressing or tearing of tissues.[5] A wider jaw aperture can help place tissue more easily in the jaws with less manipulation of the tissue and can enable more full transections in cases where there is a desire not to force fragile tissue into the jaws past what a smaller opening would allow.

Recently, a new surgical stapler has been designed for one-handed use with improved control and access by incorporating powered continuous articulation, a wider articulation angle, and a larger jaw aperture. This study was undertaken to evaluate the performance characteristics of the Echelon 3000 Stapler (Figure 1) in bench top models. Test measures included access comparison, leak testing, staple formation in thick tissue, and end effector stability in comparison to another marketed stapler.

Methods

Devices used in this study were the Echelon 3000 Stapler (ECH3, Model No. ECH60S/ECH45S, Ethicon, Inc., Cincinnati, OH), and Signia™ Powered Stapler with Tri-Staple Technology (SGN, Model No. EGIA60AMT, Medtronic, Fridley, MN).

Pelvic Anatomy Measurements: Anatomical measurements were derived from an earlier study[6] based on Pelvic Computed Tomography and Magnetic Resonance Imaging of cadavers. Scans from 9 males with heights and weights representative of the 50th percentile were converted to 3-dimensional stereolithography files with colon and pelvic structures isolated. The subjects were in the range of 60 ± 16 years, height 175 ± 4 cm, and weight 81 ± 5 kg. The measurements obtained were similar to an independent study.[7] Male patients were used because the narrowness of their pelvis creates a more challenging Low Anterior Resection (LAR) procedure than for a female patient. Pelvic anatomy of the female is round-shaped, larger, and wider, compared to the male pelvis that is heart-shaped, longer, and narrower.[8]

Access Comparison: The difficulty of performing procedures in the pelvis was examined via an analysis of factors affecting the outcomes of a total mesorectal excision. Both operative time and morbidity have been found to be dependent upon BMI, tumor distance from the anal verge, tumor depth and pelvic outlet.[7]

Predictive modeling of LAR transection was performed using virtual ECH3 and SGN staplers in the pelvic model (Figure 2). Comparisons were made on the perpendicularity of the cutline and the possibility of one or two firings completely dissecting the colon with the surgical procedure conducted at different distances above the dentate line. Optimally, when performing LAR procedures, surgeons strive to maximize the perpendicularity to the rectum, and minimize the number of firings (one firing is preferred, but no more than two).[9]

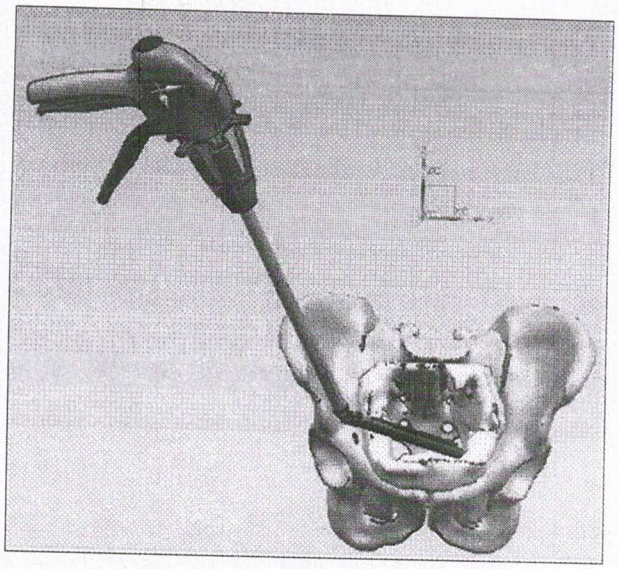

Figure 2 Virtual placement of the stapler within the pelvis at a specific distance above the dentate line.

The geometries of the surgical staplers' end effectors were placed virtually within the median scan of the 9 males. The ability of the device to completely transect the colon was determined from optimal placement at each location above the dentate line given the geometry and articulation angle constraints of the devices using a 10,000-round Monte Carlo simulation.

In the simulation, rectum width and tension factor were determined via the cadaver study; angle from perpendicular and depth of device in pelvis were derived from the CT/MRI model; and device cut line length and tissue flow factor were measured from physical testing. The tissue flow factor is defined as the ratio of the longitudinal tissue flow upon stapler closure for the test stapler compared to the control stapler. The tension factor, cut line length and flow factor were assumed to be normally distributed, rectum width to be lognormally distributed, and angle from the perpendicular to follow a triangular distribution.

During device placement within the pelvic scans, placement location and shaft angle were held constant across each device. The port was placed on the abdominal wall at the iliac crest on the patient's right side. To simulate an actual LAR procedure, the rectum model was placed at an angle within the pelvic scan. The device was placed at the target location above the dentate line. The pelvic bowl is lined with soft tissue that has some level of pliability, so a certain amount of interference, equivalent across devices, was permitted during placement.

Each device was evaluated at four different depths in the pelvic bowl: 5, 7, 9 and 11 cm from the dentate line, in correspondence with the predetermined thickness and width of the rectum. Results are provided at 7 cm from the dentate line, since this is likely the lowest location at which a 60-cm device can be used. During evaluation, shaft articulation angle did not exceed maximum capability of the device, and the end effector was positioned as perpendicularly as possible within the colon model. Once the positioning of the end effector was optimized, the angle of the end effector relative to the colon was measured.

The number of firings was calculated as:

$$No.\ of\ firings = \frac{tissue\ cutting\ distance \times tissue\ flow\ factor}{device\ cut\ line\ length}$$

The cutting distance was calculated as:

$$tissue\ cutting\ distance = \frac{colon\ width - tension\ factor}{\cos(angle\ from\ perpendicular)}$$

Results of the modeling were consistent with a study in LAR that found 50% of transections could be completed with a single firing.[10]

Leak Testing: Comparisons were made between the ECH3 and SGN for the pressure at which first leak occurred as fluid pressure was ramped up in sealed ileum. Staple firings were performed longitudinally on ex vivo porcine ileum of a selected tissue thickness range (1.75–2.25mm). The proximal end of the staple line was attached to a barbed Luer lock fitting and securely tied with a suture. The distal end was tied off with a suture. A computer-controlled pressure ramp-up rate of 30 mmHg/minute was utilized with dyed room-temperature water. Leaks were visually identified as originating from the staple line or the cut line. If a staple line leak occurred, testing was continued until there was a cut line leak. Statistical comparisons were performed at 30 through 60 mmHg via Fisher's exact test.[11,12]

Staple Form in Thick Tissue: Comparisons of staple form were made between ECH3 60mm with Green (for thick tissue, closed staple height 2.0 mm) and Black (for extra thick tissue, 2.3 mm) reloads and SGN 60 mm with Purple (for medium/thick tissue, 1.5–2.25 mm) or Black (for extra thick tissue, 2.25–3.0 mm) reloads. Evaluations were performed on the percentage of malformed staples according to Staple Form Quality (SFQ 3–5).[11] Stapling was performed on porcine stomach of target tissue thickness of 3.3 mm (Green/Purple) and 4.0 mm (Black). Statistical comparisons were made via Fisher's exact test for percentage of malformed staples.

Closure and Firing Tissue Pressure: ECH3 with GST60B and GST60G cartridges was compared to SGN with EGIA60AMT cartridge under thick tissue conditions for tissue compression during clamping and firing of porcine gastric tissue. Comparisons were performed for uniformity and peak compression pressure. Thick tissue conditions were 2.5 ± 0.1 mm for GST60B and 3.3 ± 0.1 mm for GST60G. Twelve firings were performed for each device.

The tissue compression pressures were measured on the cartridge side, which is generally higher than the anvil side. The sensor was placed at the distal end of 6th row of staples. The tissue at this point has the full history from closure to firing. The tissue beyond this point has the history of closure and firing up to the stop of the knife. The knife stop position was set at 35 mm, ie, just over half the length of the cartridge. Staples were removed at the 7–9th positions for placement of the Tekscan sensor (Tekscan, Inc., South Boston, MA). After clamping, the tissue was held in the jaws for 15 seconds prior to firing. Firing speed was set at 12mm/s. Compression pressure was monitored until the knife was stopped at the 35mm mark. Statistical comparisons were made via Student's *t*-test or Mann–Whitney for non-normally distributed data.

Tissue Grasping: Tissue grasping force was compared between ECH3 with GST60B reloads and SGN with EGIA60AMT reloads via clamping on 1.5 ± 0.3 mm thick target porcine colon tissue, cut to a length of 90 ± 5 mm. The grasping force was measured as the tissue was pulled out of the jaw, and the peak force as monitored by a 20-lbf load cell was reported as the grasping force. Tissue was grasped in the full jaw with the edge of the tissue touching the tissue stop of the jaw. Statistical comparisons were made via the Mann–Whitney test.

Shaft Stiffness: Shaft stiffness was compared between ECH3-60mm and SGN-60mm. Controlled lateral and vertical forces were applied in the middle of the jaw separately to simulate tissue manipulation forces, and the total lateral and vertical deflection of the shaft was measured. Shaft stiffness in the lateral and vertical directions was calculated from load-deflection curves. The shaft lateral and vertical stiffnesses were measured in both directions since devices were not necessarily designed to be symmetric.

A load of 1.0 lbf (4.45 N), which is considered to be a moderate manipulation force, was applied to the shaft in four directions; up, down, left, and right. For lateral forces, the joint de-articulation stiffness was included in the shaft deflection. For vertical forces, the joint vertical stiffness was included in the shaft deflection. Forces were applied to the middle of the jaw (30mm point). Statistical comparisons were made via Student's *t*-test or Mann–Whitney for non-normally distributed data.

End Effector Stability: End Effector stability during firing of ECH3-60mm devices with Green or White (for vascular/thin tissue, closed staple height 1.0 mm) reloads was compared with SGN with Medium/Thick and Vascular/Medium reloads. Four devices were applied on thick tissue thickness (3.3mm) and another four on vascular tissue. Each device was fired seven times over a range of articulation angles in a bespoke fixture. Maximum angle change of the articulation

angle was determined during the firing. Statistical comparisons were made via Student's *t*-test or Mann–Whitney for non-normally distributed data.

Surgeon Evaluation: To evaluate the usability of the ECH3, a panel of surgeons performed simulated surgical procedures on a bench top trainer with harvested tissues. Thoracic surgeons performed a pulmonary artery transection, bronchus transection and a lung parenchyma transection. Upper GI (Bariatric, Gastric, General) surgeons performed a gastric transection and a Roux-en-Y transection. Lower GI (Colorectal, General) surgeons did an LAR transection and a jejunum-to-jejunum anastomosis transection.

Following the simulated procedures, participants answered a series of assessment questions related to the operation of the device, the placement of the device on tissue and difficulty accessing and manipulating the tissue compared to the device each participant currently uses. All participants had the opportunity to review the instructions for use prior to beginning their tasks.

Each study participant signed a consent form prior to the evaluation and interview. No procedures were performed on humans or live animals. Because this was a non-interventional study (ie, a survey), ethical approval was not required.

Results

Via metrology, ECH3 had a wider angle of articulation, larger aperture and longer joint length (Table 1). Articulation span of ECH3 is 24–27% greater than SGN, and jaw aperture is 39–57% greater. To provide the greater articulation span and jaw aperture, the joint length of ECH3 is slightly larger than SGN. Placement for lower anterior resection is feasible for both staplers.

Access and Probability of Complete Transection: At 7 cm above the dentate line, the ECH3 60mm device had a 30% higher chance to complete a transection with one firing than SGN 60mm, while ECH3 45mm device had 2.4 times the chance as SGN 45mm (Figure 3). ECH3 devices had similar perpendicularity angles to the corresponding SGN devices, similar or longer cutline lengths and significantly less longitudinal tissue flow upon closure.

Leak Pressure: ECH3 exhibited a 25% greater median pressure at first leak than SGN ($p = 0.014$) (Figure 4). ECH3 had 88% fewer leaks below 40 mmHg ($p = 0.013$) and 67% fewer leaks below 50 mmHg ($p = 0.023$).

Staple Form: ECH3 produced 95% fewer malformed staples in 3.3 mm thick tissue and 72% fewer malformed staples in 4.0 mm thick tissue ($p < 0.001$ for both).

Closure and Firing Tissue Pressure: At both thicknesses, 2.5 and 3.3 mm, ECH3 had higher closure pressures than SGN, and lower firing pressures. Hence, there was less difference between closure and firing pressures for ECH3 compared to SNG, providing more uniform compression throughout the application.

Grasping Force: Average peak grasping force on 1.5mm porcine tissue was approximately two times higher for ECH3 compared to SGN.

Shaft Stiffness: Deflection of the shaft under a 1.0 lbf (4.45 N) force was greater for SGN than ECH3 both vertically and horizontally (Figure 5). In particular, deflection in the rightwards direction was over eight times greater for SGN than ECH3.

End Effector Control: In end effector stability testing, ECH3 display 79% less angular movement than SGN in thick tissue and 93% less movement on vessels (Figure 6).

A total of 45 surgeons participated in the survey. Surgeons represented the areas of thoracic, bariatric, colorectal, and general surgery. Summarized results of the questionnaires are given in Table 2. Throughout the three categories of precise placement, one-handed operation and overall, surgeons agreed significantly more often than disagreed with every benefit statement. There were no dissenting opinions on the value of a larger jaw aperture or greater articulation angle of the ECH3.

Discussion

Surgical staplers have become an indispensable tool in minimally invasive procedures. As technology has enabled their miniaturization, the use of staplers has been integral in the advancement of laparoscopic procedures, which provide

Table 1 Comparisons of ECH3 and SNG

Measure	ECH3	SGN	p-value
Articulation Span	45mm: 112° 60mm: 114°	45mm: 90° 60mm: 90°	NA
Jaw Aperture	45mm: 19.5 mm 60mm: 22.8 mm	45mm: 12.4 mm 60mm: 16.4 mm	NA
Joint Length	32 mm	27 mm	NA
Perpendicularity	45mm: 61.9° 60mm: 56.6°	45mm: 63.5° 60mm: 58.4°	NA
Cutline Length	45mm: 41.4 mm 60mm: 53.4 mm	45mm: 37.7 mm 60mm: 54.0 mm	NA
Tissue Flow upon Closure	1.148 ± 0.617 mm	3.261 ± 2.429 mm	<0.001
Tissue Flow Factor	1.0215	1.0604	NA
Probability of complete transection after one firing	45mm: 3.6% 60mm: 19.4%	45mm: 1.5% 60mm: 14.9%	NA
Probability of complete transection after two firings	45mm: 98.4% 60mm: 99.9%	45mm: 88.8% 60mm: 99.8%	NA
Leak Pressure Mean ± St Dev Median ≤30 mmHg ≤40 mmHg ≤50 mmHg ≤60 mmHg	 73.2 ± 24.1 mmHg 65.0 mmHg 0/30 (0.0%) 1/30 (3.3%) 4/30 (13.3%) 11/30 (36.7%)	 60.4 ± 27.2 mmHg 52.2 mmHg 1/32 (3.1%) 9/32 (28.1%) 13/32 (40.6%) 20/32 (62.5%)	 – 0.014 1.000 0.013 0.023 0.074
% Malformed Staples 3.3 mm 4.0 mm	 0.10% 0.40%	 2.06% 1.41%	 <0.001 <0.001
Closure Pressure	2.5mm: 154.3 kPa 3.3mm: 183.1 kPa	2.5mm: 64.7 kPa 3.3mm: 98.1 kPa	<0.001 <0.001
Firing Pressure	2.5mm: 1561.7 kPa 3.3mm: 1535.5 kPa	2.5mm: 1717.5 kPa 3.3mm: 1676.1 kPa	0.070 0.127
Pressure Difference	2.5mm: 1407.2 kPa 3.3mm: 1352.1 kPa	2.5mm: 1652.7 kPa 3.3mm: 1578.2 kPa	0.013 0.022
Peak Grasping Force	15.3 ± 3.0 N	5.23 ± 2.02 N	<0.001
Shaft Deflection Leftwards Downwards Rightwards Upwards	 1.93 ± 0.54 mm 0.96 ± 0.14 mm 1.58 ± 0.48 mm 0.92 ± 0.09 mm	 10.82 ± 1.89 mm 7.72 ± 0.49 mm 15.42 ± 1.24 mm 6.44 ± 0.50 mm	 0.003 <0.001 0.003 <0.001
End Effector Stability Thick tissue Vascular tissue	 1.01° ± 1.05° 0.35° ± 0.51°	 4.91° ± 1.77° 5.15° ± 2.62°	 <0.001 <0.001

multiple benefits over conventional open surgery.[13] However, there are a number of challenges with the use of staplers in laparoscopic procedures that need to be addressed either in the design of the stapler or by its application by the surgeon.[14]

With open surgery, the surgeon has tactile access to the tissue and a relatively wide field, with few restrictions on the design of instrument. In laparoscopy, a stapler is necessarily limited in size in order to fit through a trocar, and compression of the staples must take place perpendicularly to the shaft axis. Because of this mechanical disadvantage,

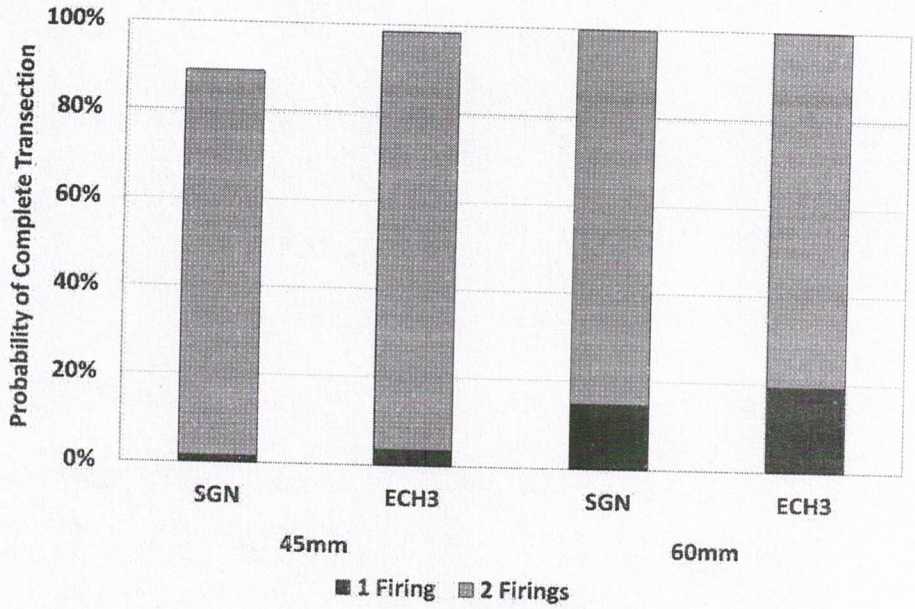

Figure 3 Probability of completing transection at 7 cm above the dentate line for one and two firings.

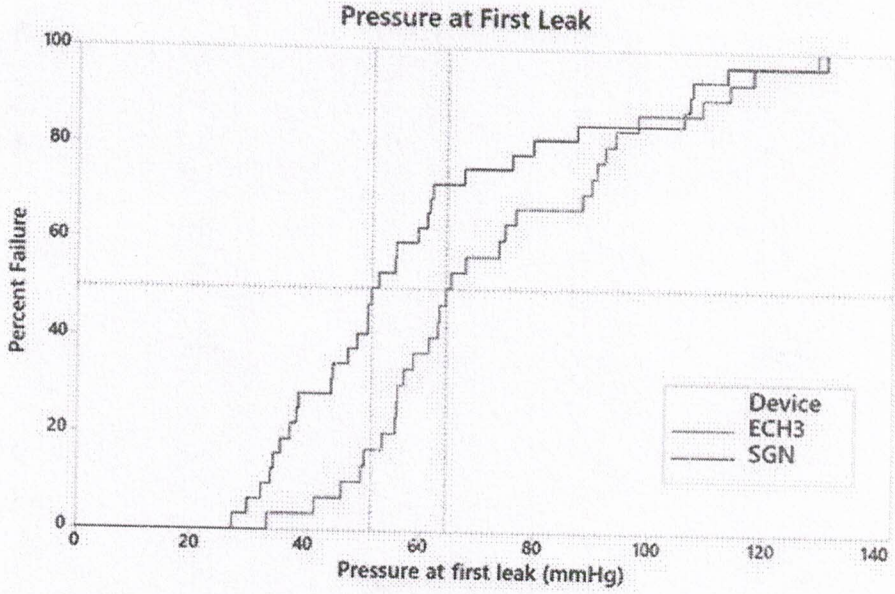

Figure 4 Pressure at first leak cumulative failure plot for ECH3 and SGN with index lines for 50% failure.

laparoscopic staplers must be designed to adapt to variable viscoelasticity within different tissues. One approach to meet these challenges is the use of powered firing, which provides the surgeon with exquisite control of the speed and strength of staple formation independent of the positioning of the device.

Previous to ECH3, the ECHELON FLEX™ Powered Plus stapler was designed to address many of the challenges that minimally invasive surgery introduced.[15] With this device, dynamic firing allows the motor to slow the firing speed when the device engages thicker tissue. A refined anvil curvature as well as wider, tapered staple pockets helped to improve the capture and formation of the staples when the device is fired.

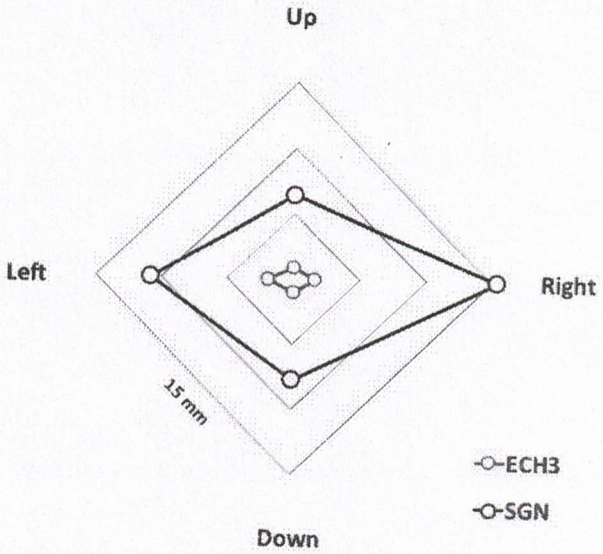

Figure 5 Deflection of shaft under a 1.0 lbf (4.45 N) load.

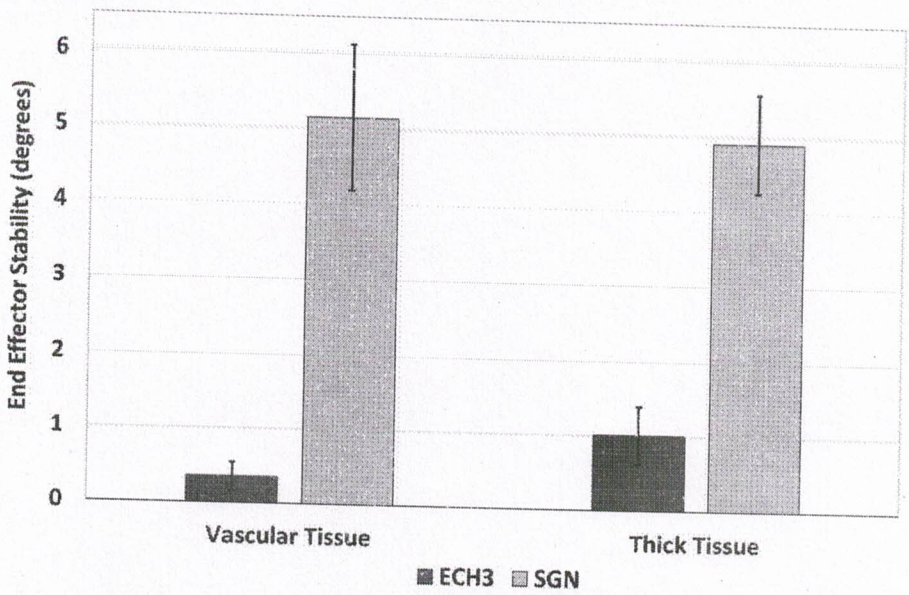

Figure 6 End effector stability of ECH3 and SGN for vascular and thick tissue.

The new stapler evaluated in the current study incorporates the advances of the previous version and adds several features to improve its utility and functionality. The Echelon 3000 Stapler is designed to deliver improved access and precision with a greater articulating range and jaw aperture. Via proprietary software, ECH3 has simple haptic and audible device feedback. Articulation adjustments can be made by 1° increments, articulation can be performed with the jaws partially closed, and the left or right articulation buttons always move the end effector in the same direction even when the jaws are rotated upside down due to the inclusion of an orientation sensor.

The joint length of ECH3 (distance from the shaft pivot point to first staple) is reduced compared to the previous version and similar to SGN. This change enables a tighter/smaller turning radius in constrained conditions. In post-use

Table 2 Summary of Results from the Surgeon Questionnaire on the Echelon 3000 Stapler

Category	Statement	Total Agree	Neutral	Total Disagree	p-value
Precise Placement	Precise placement of the end effector was easier with the test device compared to my usual device.	19	17	6	0.015
	The larger jaw aperture of the test device helps with placement on thick tissue/buttress usage.	25	17	0	<0.001
	The greater articulation angle of the test device was better for LAR and/or pulmonary artery, gastric and/or bowel placement.	25	17	0	<0.001
One-handed Operation	I could articulate the test device end effector with one hand.	37	1	4	<0.001
	I could close, fire and return with one hand with the test device.	38	2	2	<0.001
	The test device enabled simple, one-handed operation.	31	4	7	<0.001
	The auto knife return function after firing completion, and/or activation of home button, made the test device easier to use than my usual device.	23	12	7	0.005
	It is important to prevent articulation/rotation when the device is closed on a critical structure.	34	0	8	<0.001
Overall	Overall, based on today's experience, I prefer the test device to my usual device.	21	15	6	0.006

Note: Statistical evaluation was based on comparison of the total number of Agree and Strongly Agree vs the total number of Disagree and Strongly Disagree.

surveys, surgeons agreed that the operation (placement and transection, articulation, rotation, closure, firing and opening) of ECH3 could easily be performed with one hand.

Colorectal surgeons try to minimize the number of firings when performing lower anterior resection (LAR), due to anastomotic leak factors.[16,17] For restorative rectal resection, the odds ratio for anastomotic leakage was 2.71 (95% CI 1.17–6.26) when three or more firings were used.[9] The greater likelihood of a single transection increases surgical efficiency that may result in reduced risks of complications caused by crossing staple lines.[18]

In a virtual surgery model, the ECH3 stapler was more likely to complete an LAR transection both within one and two firings compared to another marketed stapler. The three key factors in determining the number of firings are considered to be access perpendicularity, tissue flow (milking) during compression and cutline length. ECH3 achieved similar perpendicularity to SGN but had both reduced tissue flow and slightly greater cutline length. Fewer firings observed for ECH3 may be due primarily to superior tissue manipulation from Gripping Surface Technology, which limits milking during compression.

ECH3 showed higher pressures at first leak and a lower rate of leakage in the critical range between 30 and 60 mmHg.[12] This may be due in part to fewer malformed staples that can compromise the integrity of the staple line and raise the risk of unexpected complications.[19] The staple form for ECH3 showed fewer malformed staples both in medium and thick tissue compared to a competitive brand. Properly formed staples in laparoscopy are difficult, especially in thick tissue.[14] The improved anvil and dynamic firing speed may result in improved staple form, as has been confirmed in recent studies on similar devices.[15,20]

In grasping the tissue, it is important that the stapler applies a consistent pressure to the tissue to achieve optimum staple formation and prevent the tissue from "milking" out of the end effector. The ECH3 Gripping Surface Technology (GST) consisting of indentations in the cartridge surface is designed to increase the ability of the stapler to grasp tissue.[21–24] Manipulation of the tissue will also be aided by a robust shaft that does not deflect under moderate pressure. In this study, the

ECH3 had a more uniform compression, stronger grasping force and a stiffer shaft than a competitive stapler. All these qualities help explain why the ECH3 provides greater stability of the end effector and improved access to the target tissue.

The Echelon 3000 Stapler design includes an adjustable powered articulation, a greater articulating range and wider jaw aperture. In this study, improved access capability, stronger seals, fewer malformed staples, greater grasping force and end effector stability were demonstrated. These advantages were recognized by surgeons who evaluated the use of the device preclinically. Clinical studies are needed to determine if the new features of this device confer significant patient benefits.

Disclosure

All authors are employees of Ethicon, Inc., the manufacturer of the Echelon 3000 Stapler. The authors report no other conflicts of interest in this work.

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