

16 settembre 2015

A: Responsabili della sicurezza e Chirurghi

Oggetto: **AVVISO URGENTE RELATIVO ALLA SICUREZZA SUL CAMPO**

Prodotti interessati: 00-2228-024-00 Filo guida con punta a proiettile, diam. 2,4 mm;
00-2255-025-00 Filo guida liscio omerale, diam. 2,4 mm, lungh. 70 cm;
00-2255-026-00 Filo guida omerale con punta a proiettile, diam. 2,4 mm,
lungh. 70 cm;
47-2237-033-00 Filo guida liscio, diam. 2,4 mm, lungh. 100 cm;
47-2237-037-00 Filo guida liscio, diam. 3,0 mm, lungh. 100 cm;
47-2237-038-00 Filo guida con punta a proiettile, diam. 3,0 mm, lungh. 100 cm;
47-2255-008-00 Filo guida con punta a sfera, diam. 2,4 mm, lungh. 70 cm;
47-2255-008-01 Filo guida con punta a sfera, diam. 3,0 mm, lungh. 100 cm

Tutti i lotti distribuiti, non scaduti, con scadenza di 10 anni indicata sull'etichetta (ved. Allegato 1 per un elenco completo di combinazioni dei lotti di articoli)

Zimmer Biomet sta avviando una procedura di richiamo volontario di fili guida con scadenza di 10 anni indicata sull'etichetta; infatti, da una verifica della durata dello stoccaggio delle confezioni è risultato che la scadenza dei suddetti fili guida sterili riportata sull'etichetta (etichetta sulla scatola esterna ed etichetta sulla cartella del paziente) è di 10 anni. In base ai test condotti sulle confezioni è prevista invece una scadenza di 5 anni per i medesimi fili guida. Zimmer Biomet richiama tutti i lotti di fili guida non consumati e non scaduti, sulla cui etichetta è riportata una durata dello stoccaggio di 10 anni. I lotti interessati sono stati distribuiti tra agosto 2005 e dicembre 2011. Considerata l'elevata velocità di rinnovo di questi prodotti e la frequenza degli ordini in sospenso degli stessi, si presume che la quantità di unità rimaste sul campo interessate dal presente avviso non sia notevole. Non sono state riportate ferite o lesioni relative al problema descritto.



Immagine di esempio di un filo guida nella confezione sterile

Rischi		
Conseguenze immediate per la salute (lesioni o patologie) che possono derivare dall'uso del dispositivo difettoso o dall'esposizione allo stesso.	Alta probabilità	Peggior ipotesi
	È altamente probabile che i fili guida rimangano sterili nella confezione prima dell'apertura del prodotto per un intervento chirurgico, senza conseguenze negative.	Una potenziale conseguenza a breve termine per la salute riguarda l'infezione post-operatoria dovuta all'uso di un filo guida sub-sterile.
Conseguenze a lungo termine per la salute (lesioni o patologie) che possono derivare dall'uso del dispositivo difettoso o dall'esposizione allo stesso.	Alta probabilità	Peggior ipotesi
	È altamente probabile che i fili guida rimangano sterili nella confezione prima dell'apertura del prodotto per un intervento chirurgico, senza conseguenze negative.	Le manifestazioni a lungo termine possono includere osteomielite, ascesso dei tessuti molli e sepsi.

Le sue responsabilità

1. Leggere attentamente la presente notifica e accertarsi che il personale interessato sia a conoscenza del relativo contenuto.
2. Fornire ai rappresentanti di vendita Zimmer Biomet la necessaria assistenza nella messa in quarantena dei prodotti indicati nell'elenco dell'Allegato 1.
3. Il rappresentante di vendita Zimmer ritirerà il prodotto in questione, se presente, dalla struttura interessata.
4. Compili il modulo di Certificazione di conferma da (Allegato 2) e lo restituisca a per.it@zimmerbiomet.com.
5. **Qualora dopo aver letto la presente notifica desideri porre ulteriori domande o abbia dubbi, contatti il rappresentante di vendita Zimmer Biomet locale.**

Comunicazione agli organi di vigilanza

Questa notifica volontaria verrà riportata alla Food and Drug Administration (“FDA”) americana e all'autorità competente a livello locale.

Eventuali reazioni avverse manifestate con l'uso di questi prodotti e/o problemi di qualità possono anche essere riportati secondo la Linea Guida MEDDEV 2.12-1 Rev. 8 all'autorità sanitaria locale del rispettivo paese.

Si prega di informare Zimmer GmbH di eventuali eventi avversi associati a questo dispositivo o ad altri prodotti Zimmer Biomet. Gli eventi avversi possono essere riportati a Zimmer Biomet all'indirizzo winterthur.per@zimmerbiomet.com o al rappresentante di vendita Zimmer Biomet locale.

ALLEGATO 1

Codice articolo	Numero di lotto	Codice articolo	Numero di lotto	Codice articolo	Numero di lotto	Codice articolo	Numero di lotto
00-2228-024-00	60348289	47-2237-037-00	60896539	47-2255-008-01	60412453	47-2255-008-01	61009521
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ALLEGATO 2

SI RICHIEDE RISPOSTA IMMEDIATA – SI RICHIEDE UN'AZIONE TEMPESTIVA

Certificato di conferma ZOIT ID-13:

Avviso sulla sicurezza sul campo (FSN, Field Safety Notice)/Azione correttiva di sicurezza sul campo (FSCA, Field Safety Corrective Action): 1822565-08-19-2015-010-R

Prodotti interessati: 00-2228-024-00 Filo guida con punta a proiettile, diam. 2,4 mm;
00-2255-025-00 Filo guida liscio omerale, diam. 2,4 mm, lung. 70 cm;
00-2255-026-00 Filo guida omerale con punta a proiettile, diam. 2,4 mm, lung. 70 cm;
47-2237-033-00 Filo guida liscio, diam. 2,4 mm, lung. 100 cm;
47-2237-037-00 Filo guida liscio, diam. 3,0 mm, lung. 100 cm;
47-2237-038-00 Filo guida con punta a proiettile, diam. 3,0 mm, lung. 100 cm;
47-2255-008-00 Filo guida con punta a sfera, diam. 2,4 mm, lung. 70 cm;
47-2255-008-01 Filo guida con punta a sfera, diam. 3,0 mm, lung. 100 cm

**Tutti i lotti distribuiti, non scaduti, con scadenza di 10 anni indicata sull'etichetta
(ved. Allegato 1 per un elenco completo di combinazioni dei lotti di articoli)**

Apponendo la firma sottostante, confermo di aver ricevuto e compreso il contenuto dell'Avviso urgente relativo alla sicurezza sul campo – Correzione e di aver intrapreso le azioni richieste secondo le specifiche dell'avviso.

Nome in stampatello: _____ Firma: _____

Qualifica _____ Telefono: () _____ - _____

Data: ____/____/____

Nome e indirizzo dell'ospedale:

**Nota: Si prega di compilare il modulo presente e di inviarne una copia per e-mail a: per.it@zimmerbiomet.com o via fax al nr.: 02/51626240 .
Si prega di conservare una copia della risposta ai fini di una eventuale revisione.**