Urgent Field Safety Notice

Product Name: **EIT Implants (Cervical, PLIF, TLIF) – see attached list**

FSCA-identifier: **FA-1619673**

Type of Action: **Field Safety Corrective Action**

Date: October 31, 2019

Attention: Trust Chief Executives, the Clinical Director of the Orthopaedic Department, the Orthopaedic Theatre Manager, the Safety Liaison Officer, General Managers of Private Sector Hospitals.

Model Name: EIT Cellular Titanium® Cervical Cages; EIT Cellular Titanium® Lumbar Cages – PLIF and TLIF

Type of Device: The EIT Cellular Titanium® Cervical Cages are intervertebral body fusion devices intended for use for anterior cervical interbody fusion. The EIT Cellular Titanium® Lumbar Cages – PLIF and TLIF in combination with supplemental fixation are indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2 – S1 whose condition requires the use of interbody fusion.

DePuy Spine is issuing a Field Safety Notice on behalf of the Legal Manufacturer Emerging Implant Technologies (EIT) for the parts and lot numbers of implants listed in Attachment A. This is a voluntary notification for informational purposes only, with no requirement to return impacted devices.

Reason for the Field Safety Notification:
This voluntary field safety notification is being issued because the inner blister label and the outer carton label of the affected implants have different expiration dates. The discrepancy is a result of an intentional repackaging and relabeling effort conducted by EIT. The implant shelf life was extended to 5 years following a successful validation effort. The inner label reflects the original 2-year shelf life, while the outer label reflects the updated 5-year shelf life.

Clinical Implications and Patient impact:
There are no patient risks if an implant is used within the validated 5-year shelf life displayed on the outer carton label or used within the 2-year shelf life displayed on the inner label. The products are validated for up to 5 years of shelf life and will function as intended.

If the labeling discrepancy is identified intraoperatively, a surgical delay may result while the issue is investigated. Additionally, alternative devices may be requested, which may also result in a surgical delay. Finally, if no alternative device is available, use of patient autograft may be undertaken. There have been no reported patient harms associated with the labeling discrepancy.

Steps to Take:
The purpose of this communication is to re-confirm the shelf life of the affected products and request acknowledgement of the notice. Please take the following actions:

- Utilize the expiration date displayed on the outer carton label which represents the validated 5-year shelf life; disregard the expiration date on inner blister label.
- Review this notice and complete the Business Reply Form (Attachment B) to signify that your facility has received and reviewed this notice. Return the completed Business Reply Form to your Sales Consultant within one (1) week of this notice.
- Retain a copy of the completed Business Reply Form in your files along with this notice.
- Forward this notice to others in your facility that need to be informed.
- If any affected product has been forwarded to another facility, contact that facility immediately to communicate the information in this field safety notice.
- Notify surgeons at your facility by providing them with a copy of this notice to ensure surgeons are aware of this field safety notice.
- Maintain a copy of this notice with the affected devices.
- If you would like to return the affected devices and receive replacement product, please contact your Sales Consultant.

Transmission of this Field Safety Notice:
This voluntary notice has been sent to you because our records indicate that you may have received some of the concerned products. This notice needs to be passed on to all those who need to be aware within your organization.

For any enquiries regarding this Field Safety Notice contact:
Recall Coordinator: Mona Rehmatullah
Email: mrehmatu@its.jnj.com
Tel no: +1 561-494-3036

This FSN has been shared with the appropriate Regulatory Agency.

We apologize for any inconvenience that this field safety notification may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Spine Sales Consultant.

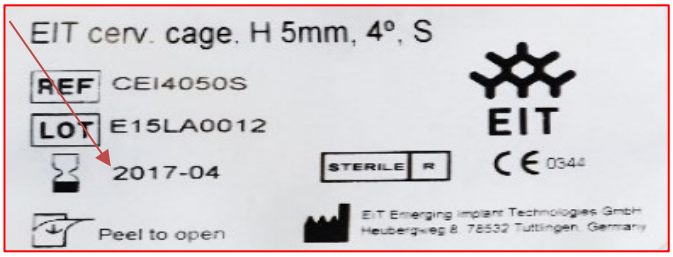
Thank you for your attention and cooperation.

ATTACHMENT 1: Product Identification Tool for EIT Implants (Cervical, PLIF, TLIF) PACKAGE.

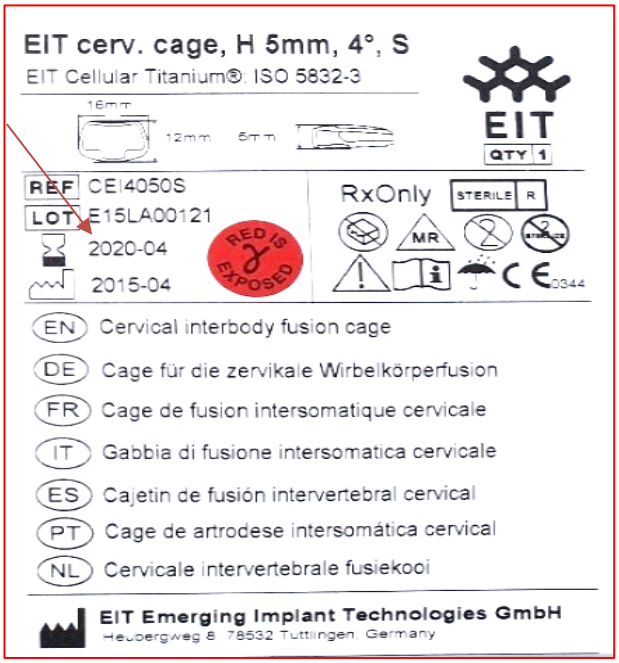
This tool will help customers identify labeling discrepancy subject to this notification by using the packaging labels.

When product issue is present, original expiration date on the inner label does not match the outer label with validated extended shelf life.

INNER BLISTER LABEL



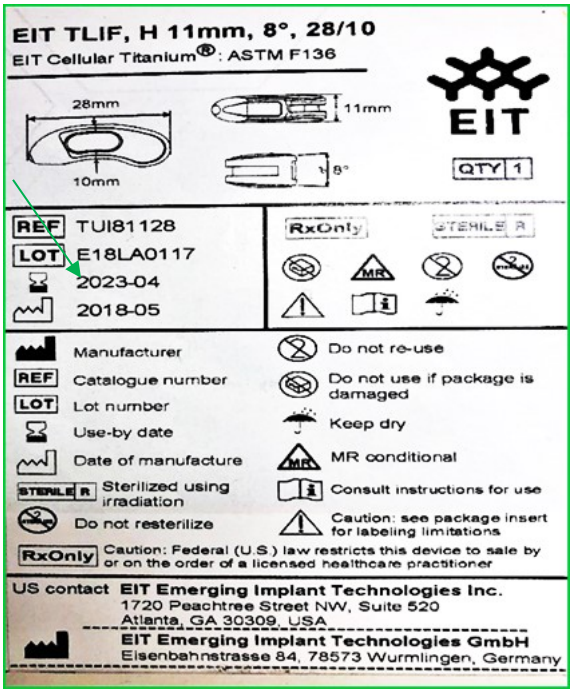
OUTER CARTON LABEL



When product issue is NOT present, the expiration date on the inner label and the outer label matches.

INNER BLISTER LABEL

OUTER CARTON LABEL



ATTACHMENT B: List of product part & lot numbers

Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number	Product Code	Lot Number
CEI4040S	E14IA00011	CEI4080S	E14LA00681	PEI80930	E15LA00601	CEI8040L	E15LA01311
CEI4040L	E14IA00021	PEI40910	E14LA00701	PEI81106	E15LA00611	CEI8050S	E15LA01321
CEI4050S	E14IA00031	PEI81126	E15IA00021	PEI81110	E15IA00621	CEI8050L	E15LA01331
CEI4070S	E14IA00071	PEI40706	E15IA00031	PEI81126	E15IA00631	CEI8060S	E15LA01341
CEI4070L	E14IA00081	PEI81326	E15LA00041	PEI81130	E15LA00641	CEI8060L	E15LA01351
CEI4040S	E14IA00101	PEI81526	E15LA00051	PEI81310	E15LA00661	CEI8070S	E15LA01361
CEI4040L	E14IA00111	PEI81330	E15LA00061	PEI81326	E15LA00671	CEI8070L	E15LA01371
CEI4050S	E14LA00121	PEI81530	E15LA00071	PEI81330	E15LA00681	CEI8080S	E15LA01381
CEI4050L	E14IA00131	CEI4040L	E15LA00081	PEI81506	E15LA00691	CEI8080L	E15LA01391
CEI4060S	E14IA00141	CEI4040S	E15IA00091	PEI81510	E15LA00701	PEI40702	E15LA01401
CEI4060L	E14IA00151	CEI4050L	E15LA00101	PEI81526	E15LA00711	PEI40902	E15LA01411
CEI4070S	E14IA00161	CEI4050L	E15LA00111	PEI81530	E15LA00721	PEI40906	E15IA01421
CEI4070L	E14IA00171	CEI4050S	E15IA00121	TEI00728	E15IA00731	PEI41106	E15IA01441
CEI4080S	E14IA00181	CEI4060L	E15IA00131	TEI00928	E15IA00741	PEI41306	E15IA01451
PEI40702	E14IA00201	CEI4060L	E15IA00141	TEI01128	E15LA00751	PEI81126	E15LA01461
PEI40902	E14IA00211	CEI4060S	E15IA00151	TEI01328	E15LA00761	PEI81306	E15LA01471
PEI41102	E14LA00221	CEI4070L	E15IA00161	TEI01528	E15IA00771	CEI4050S	E15LA01481
PEI41302	E14IA00231	CEI4070S	E15LA00171	TEI00732	E15LA00781	CEI4060L	E15LA01491
PEI40706	E14IA00241	TEI00728	E15IA00181	TEI00932	E15IA00791	CEI4060S	E15LA01501
PEI40906	E14LA00251	TEI00928	E15IA00191	TEI01132	E15IA00801	CEI4070L	E15LA01511
PEI41106	E14IA00261	TEI01128	E15LA00201	TEI01332	E15LA00811	CEI4070S	E15LA01521
PEI41306	E14IA00271	TEI01328	E15IA00211	TEI01532	E15IA00821	PEI40902	E15LA01531
PEI41506	E14LA00281	TEI01528	E15IA00221	TEI80928	E15IA00831	PEI81126	E15LA01541
PEI80906	E14LA00291	TEI00732	E15IA00231	TEI81128	E15LA00841	PEI81326	E15LA01551
PEI81106	E14LA00301	TEI00932	E15IA00241	TEI81328	E15IA00851	PEI40702	E15IA01561
PEI81306	E14LA00311	TEI01132	E15IA00251	TEI81528	E15LA00861	PEI40706	E15LA01571
PEI81506	E14LA00321	TEI01332	E15IA00261	TEI80932	E15IA00871	PEI40726	E15LA01581
PEI41110	E14IA00341	TEI01532	E15LA00271	TEI81132	E15LA00881	PEI40902	E15LA01591
PEI41310	E14LA00351	TEI80928	E15IA00281	TEI81332	E15IA00891	PEI40906	E15LA01601
PEI41510	E14LA00361	TEI81128	E15IA00291	TEI81532	E15IA00901	PEI41102	E15LA01611
PEI80910	E14LA00371	TEI81328	E15IA00301	TEI00728	E15IA00961	PEI41106	E15IA01621
PEI81110	E14LA00381	TEI81528	E15LA00311	TEI00928	E15LA00971	PEI41302	E15LA01631
PEI81310	E14LA00391	TEI80932	E15IA00321	TEI01128	E15LA00981	PEI41306	E15IA01641
PEI81510	E14LA00401	TEI81132	E15LA00331	TEI01328	E15LA00991	PEI41326	E15LA01651
PEI40726	E14LA00411	TEI81332	E15LA00341	TEI01528	E15LA01001	PEI41330	E15LA01661
PEI40926	E14LA00421	TEI81532	E15LA00351	TEI00732	E15LA01011	PEI80906	E15LA01671
PEI41126	E14LA00431	PEI40702	E15LA00361	TEI00932	E15LA01021	PEI80926	E15LA01681
PEI41326	E14IA00441	PEI40706	E15IA00371	TEI01132	E15LA01031	PEI81106	E15LA01691
PEI41526	E14LA00451	PEI40726	E15LA00381	TEI01332	E15LA01041	PEI81110	E15LA01701
PEI80926	E14LA00461	PEI40902	E15IA00391	TEI01532	E15LA01051	PEI81130	E15LA01711
PEI81126	E14IA00471	PEI40906	E15LA00401	TEI80928	E15IA01061	PEI81306	E15LA01721
PEI81326	E14IA00481	PEI40910	E15LA00411	TEI81128	E15IA01071	CEI8070S	E15LA01751
PEI81526	E14IA00491	PEI40926	E15LA00421	TEI81328	E15LA01081	PEI81106	E16LA00011
PEI40930	E14LA00501	PEI40930	E15LA00431	TEI81528	E15LA01091	PEI81306	E16LA00021
PEI41130	E14IA00511	PEI41102	E15IA00441	TEI80932	E15LA01101	PEI80910	E16LA00031
PEI41330	E14LA00521	PEI41110	E15LA00451	TEI81132	E15IA01111	PEI81110	E16LA00041
PEI41530	E14LA00531	PEI41130	E15LA00471	TEI81332	E15LA01121	PEI41306	E16LA00061
PEI80930	E14LA00541	PEI41302	E15LA00481	TEI81532	E15LA01131	PEI41510	E16LA00071
PEI81130	E14LA00551	PEI41306	E15IA00491	PEI40706	E15IA01141	CEI4040S	E16LA00081
PEI81330	E14IA00561	PEI41310	E15LA00501	PEI40906	E15IA01151	CEI4050S	E16LA00091
PEI81530	E14IA00571	PEI41326	E15IA00511	PEI80906	E15LA01171	CEI4060S	E16LA00101
CEI4040S	E14IA00601	PEI41330	E15LA00521	PEI81106	E15IA01181	CEI8040L	E16IA00121
CEI4040L	E14LA00611	PEI41506	E15LA00531	PEI81326	E15LA01201	CEI8070S	E16IA00141
CEI4050S	E14IA00621	PEI41510	E15LA00541	PEI81526	E15LA01211	CEI8080L	E16LA00151
CEI4050L	E14IA00631	PEI41526	E15LA00551	PEI81126	E15IA01261	CEI8080S	E16IA00161
CEI4060S	E14IA00641	PEI41530	E15LA00561	PEI80906	E15LA01271	TEI80928	E16IA00231
CEI4060L	E14IA00651	PEI80906	E15LA00571	PEI41106	E15IA01281	TEI81132	E16IA00251
CEI4070S	E14IA00661	PEI80910	E15IA00581	CEI4080L	E15IA01291	CEI4080L	E16LA00281
CEI4070L	E14IA00671	PEI80926	E15LA00591	CEI8040S	E15LA01301		

Attachment C - Business Reply Form

This Letter acknowledges receipt of the Field Safety Notice related to labelling discrepancy due to extension of shelf life of the affected products listed in Attachment B.

FSCA Identifier: FA-1619673

Please fax or e-mail this completed document to **[**INSERT DePuy Marketing Company/Affiliate contact details**]**

☐ Yes, I have read and understand the notification

Comments (if any):

Print Name: _____

_____

Signature

_____

Hospital Name

_____

City

_____

Country

_____

Telephone Number or E-mail Address