



NVT Spring Symposium:



Extractables and Leachables: a concern for our health?

Sections Pharmaceutical Toxicology & Risk Assessment

15 April 2025

Extractables and leachables

Implant Failure: STRATOS System for Pectus Repair



Prashant K. Sharma, PhD, Tineke P. Willems, PhD, Daan J. Touw, PhD,
Willem Woudstra, BAsC, Michiel E. Erasmus, PhD, and Tjark Ebels, PhD

Departments of Biomedical Engineering, Radiology, Clinical Pharmacy and Pharmacology, and Cardiothoracic Surgery, University Medical Center Groningen, University of Groningen, Groningen, Netherlands

(Ann Thorac Surg 2017;103:1536–43)

© 2017 by The Society of Thoracic Surgeons

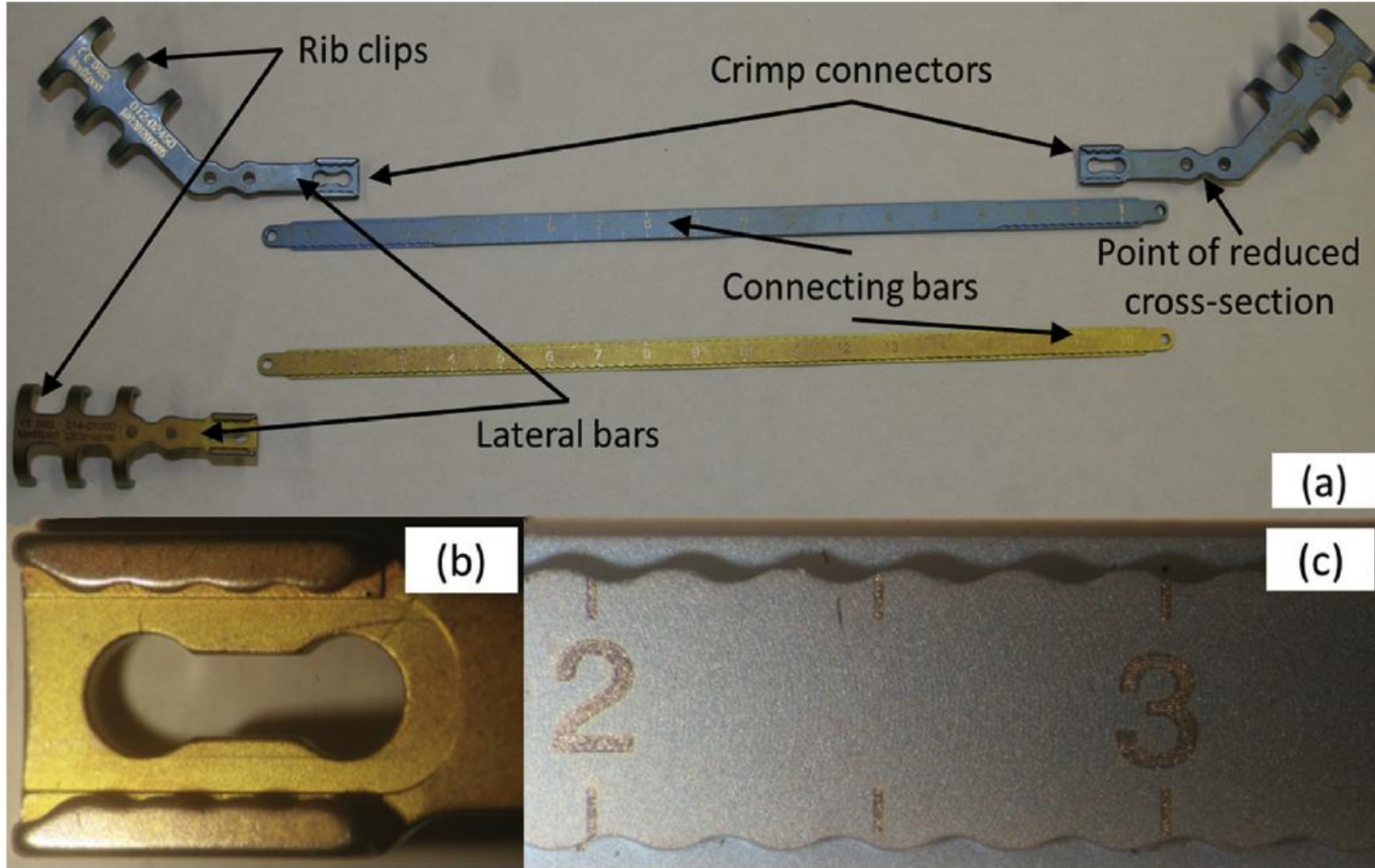


Fig 1. (a) Different parts of the STRATOS implant; (b) the crimp connector; and (c) the connecting bar.

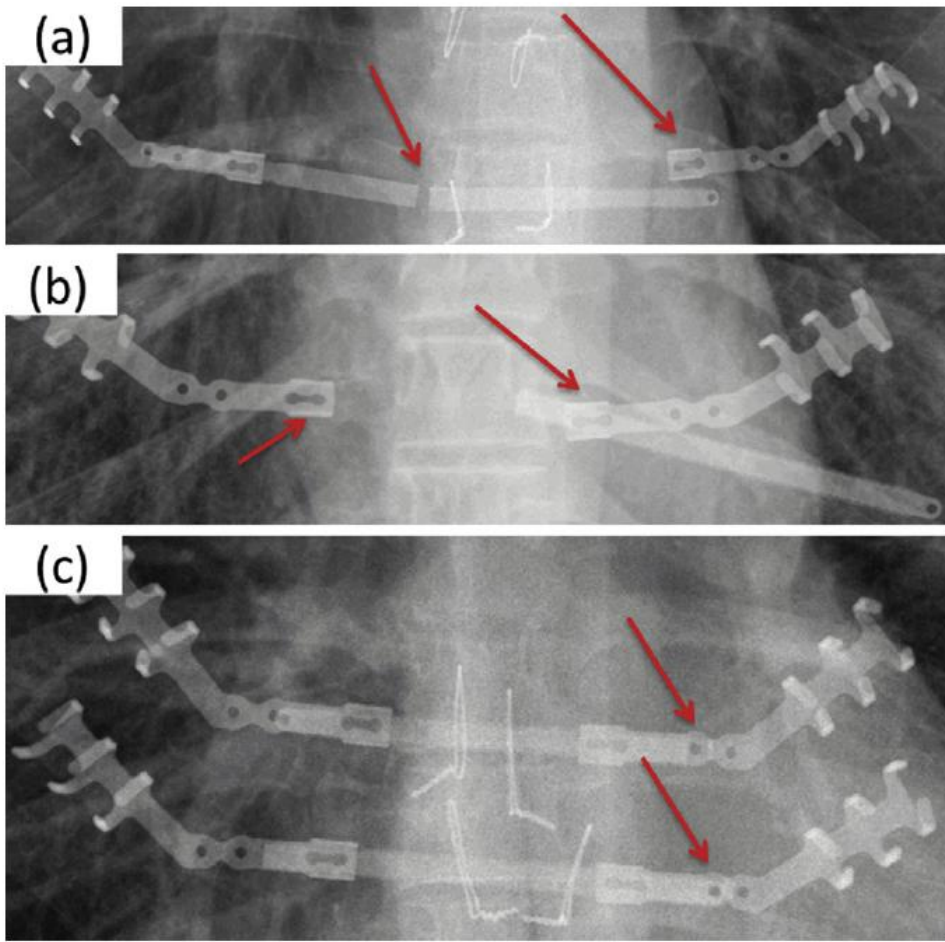


Fig 2. Single or multiple failures (red arrows) observed *in vivo* for (a, b) single and (c) double STRATOS implants placed for pectus correction from December 14, 2011, to July 18, 2013, at University Medical Center Groningen. (a) and (b) also show loose implant pieces freely floating in the cardiothoracic region.

Table 1. Different Types of Failures Observed in Explanted STRATOS Implants Placed in 12 Patients for Pectus Correction

Patient No.	Bars (n)	Symptoms	Failures (n)	F _{CB}	L _{CC}	F _{RC}	Ti/g Tissue ^a (mg)	Implantation to Diagnosis (days)	Recurrence After Removal
1 ^b	1	No	2	1	1	0	10.5	896	No
2	1	No	1	0	0	1		862	No
3	2	Sudden pain	1	0	0	1		817	No
4 ^b	1	No	2	1	0	1	0.4	840	No
5 ^b	1	No	2	0	1	1	2.0	792	No
6 ^b	1	No	3	0	2	1	1.5	660	No
7	1	Intermittent pain	2	0	2	0		583	No
8	2	Chronic pain	2	0	0	2		118	Yes, reoperation with Nuss bar
9	1	Chronic pain	1	1	0	0		231	Yes, reoperation with Ravitch procedure
10 ^b	1	No	2	1	1	0	1.0	776	Yes, declined reoperation
11	1	No	1	0	1	0		387	No
12 ^b	2	No	4	3	0	1	1.6	314	Yes, reoperation with Nuss bar
Total	15	...	23	7	8	8

^a Amounts of titanium (Ti) per gram tissue determined by atomic absorption spectroscopy.

^b Indicates simultaneous tissue biopsy.

This table summarizes all the figures from the supporting material.

F_{CB} = fracture in connecting bar; F_{RC} = fracture in rib clip at reduced cross-section; L_{CC} = loosening and failure of crimp connector; No. = number; STRATOS = Strasbourg Thoracic Osteosyntheses System.

Program

12:50 – 13:25	Extractables and leachables from syringes. Tine Folkertsma and Angela Aalbers, Martini hospital, Groningen.
13:25 – 14:00	Risk Assessment Manufacturing Related Leachables & Extractables – Example from Industry. Yolanda Ponstein, Pharming Technologies, Leiden
14:00 – 14:30	Coffee & Tea break
14:30 – 15:05	Leachables from food contact materials & products in contact with drinking water. Bianca van de Ven, RIVM, Bilthoven
15:05 – 15:40	You only see it when you know it: effects of exposure to 'medical devices' Prof. dr. Albert J. Feilzer, Em. Professor of General Dentistry
15:40 – 15:55	Panel discussion , moderated by Marjolijn Woutersen
15:55 – 16:00	Closure by Daan Touw
16:00 – 17:30	Drinks



0 antwoord verzonden

With which audience group do you identify yourself?

De QR scannen of
de koppeling
gebruiken om deel
te nemen



<https://forms.office.com/r/mrZJqk9pPk>

 Koppeling kopiëren

Industry

Academic

Government

NGO

Treemap

Bar



1 van 16

