HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Safety Notice

Medical Devices

Sterile Forceps

Priority 1 – For Immediate Action

HPRA Safety Notice: SN2015(18) **Issue Date: 15 July 2015**

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Zethon Limited	V24802

ISSUE
Zethon Limited advised that these forceps may not be sterile.

ACTION OR RECOMMENDATIONS
The HPRA advises that users: 1 Please forward this safety notice to appropriate personnel within your organisation and to any centres/organisations where these devices may have been transferred to. 2 Immediately identify the location of all the affected forceps and quarantine these products. 3 If you / your institution have any affected forceps, please contact MED Surgical to arrange collection of the affected forceps.

TARGET GROUPS

Hospital CEOs Risk Managers Procurement Managers	Supplies Staff Theatre Staff

BACKGROUND

Zethon have confirmed that the following products are affected:

Part numbers: AV-950, AV-952, AV-953, BAF2015-05, BAF2015-10, BMF2010-05, BSF2015-05, BSF2015-10, BSF2015-20, BSF2020-05, BSF2020-15, BSF2020-20, BYF2020-10, BYF2020-20, CM-090/1-D, CM-094/1B-D, CM-094/1-D, CM-094B-D, CM094-D, CM-06/1-D, CM-096, CM-098/22-D, CM-099-D, CM-099, EM-091/D, EM-094/1-D, EM-094/21-D, EM-098/24A-D, EM-098/24DW/A, EM-099-D, PH-091/201D, PH-094/10.5D, PH-096/181D, REM-090/1-D, REM-091/6-D, REM-091-D, REM -092/4-D, REM-094/1B-D, REM-94/1-D, REM-094-D, REM-095/4-D, REM-095-D, REM-095-DS, REM-096/15-D, REM-096/1-D, REM-096-D, REM-097/1-D, REM-098/1-D, REM-098/21-D, REM-098/22-D, REM-098-24-D, REM-098/2A-D, REM-098-D, REM-099-D, REM-099-DNS, VC-094-D, VC-096-D, VC-099-D, YSO-9225, YSO-9325, YSO-9425, YSO-9625.

Batch numbers: 238, 340, 341, 342, 343, 2038, 2039, 2041, 2043, 2044, 2047, 2048, 2049, 2050, 2051, 2053, 2056, 2057, 2059, 2060, 2061, 2062, 2063, 2072, 2073, 2074, 2075, 2080, 2082, 2083, 2086, 2087, 2088, 2089, 2090, 2093, 2094, 2095, 2096, 2097, 2098, 2101, 2102, 2103, 2105, 2106, 2107, 2108, 2109, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2127, 2128, 2129, 2130, 2133, 2136, 2137, 2138, 2144, 2147, 2148, 2150, 2151, 2152, 2156, 2160, 2161, 2162, 2165, 2168, 2169, 2172, 2184, 2186, 2187, 2188, 2189, 2192, 2194, 2195, 2196, 2197, 2198, 2199, 2202, 2203, 2207, 2208, 2209, 2212, 2213, 2176L, 2200L, R2162, R2181, R2187, R2188, R2189, R2198, R2207, R2208, R2209.

Full details of the field safety corrective action can be found in the attached field safety notice issued.

MANUFACTURER & DISTRIBUTOR CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Zethon Limited
2 Halton Brook Business Park
Weston Road
Aston Clinton
Bucks HP22 5WF
England

Telephone: +44-1296-634090
E-mail: vigilance@zethon.com
Website: www.zethon.com

Enquiries to the **distributor** should be addressed to:

MED Surgical
Howth Junction Business Centre
Dublin 5

Telephone: 01-8391511
E-mail: marie@med.ie
Website: www.medsurgical.ie

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
Website: www.hpra.ie