

To the attention of: Hospital Personnel

08 July 2016

URGENT NOTICE:
Field Safety Notice – Product Removal – R421630
Adapter for Colibri, for Electric Pen Drive (05.001.024)
Adapter, small, for Colibri (II) and Small Battery Drive (II) (05.001.108)

Part Description, Part Number and Serial/Lot Numbers

Product Descriptions	Part Number	Serial/Lot Numbers
Adapter for Colibri, for Electric Pen Drive	05.001.024	Lot# :1352144, 1468093, PA043998, 1467714, 1394645, 1544631, PA043998
Adapter, small, for Colibri (II) and Small Battery Drive (II)	05.001.108	See Attachment 1 for Serial Numbers

Dear Sir/Madam,

Synthes GmbH is initiating a product removal of the above listed lot(s) of the Adaptor for Colibri and the serial numbers identified in attachment 1 of the small Adaptor for Colibri II and Small Battery Drive II.

The Adaptors (05.001.024 and 05.001.108) can be used with one of the electrical consoles belonging to the Electric Pen Drive (EPD) System (05.001.000, 05.001.001, 05.001.002 or 05.001.006) to operate the Colibri and Colibri II with the EPD consoles. The adaptor can be inserted into the Colibri or Colibri II handpiece and removed like a battery pack.

Our records indicate that you may have inventory that is impacted or have been using affected product(s).

Reason for the Notice: Synthes has determined there is a potential for the Adapter for Colibri and small Adapter for Colibri II and Small Battery Drive and Small Battery Drive II to generate excessive internal pressure that may cause the respective products to burst. Although preliminary internal tests for this failure mode have determined this scenario is highly unlikely to occur, Synthes has decided to remove these products from the field.

Potential hazard: The products subject to this product removal could cause permanent injury to the user and/or patient.

Customer immediate actions:

Please verify whether you have any of the affected products and take the following actions, as appropriate.

If you **DO HAVE** any of the identified affected product(s), please take the following steps:

- Ensure anyone in your facility impacted by this notification reads this letter carefully.
- Immediately identify and quarantine all products listed above in a manner that ensures the affected products will not be used.
- Maintain a copy of this communication with any affected product(s) identified above.
- Complete the Verification Section (page 3 of this letter) by checking the appropriate box indicating affected product has been located. Also, please indicate the number of devices found and their

serial number. Please include your name, title, address, telephone number, signature and date in the spaces provided.

- Return the completed Verification Section to your local DePuy Synthes contact person.
- Contact your local DePuy Synthes sales organisation to arrange the return of the affected devices for a replacement.

If you **DO NOT HAVE** any of the identified affected product(s), please take the following steps:

- Complete the attached Verification Section (page 3 of this letter) by checking the appropriate box indicating that no affected product has been located. Please include your name, title, address, telephone number, signature and date in the spaces provided. This return documentation acknowledges your receipt of medical device product removal information.
- Return the completed Verification Section to your local DePuy Synthes contact person.

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on page 3 of the notification.

If any of the affected products has been forwarded to another facility, contact that facility to arrange return and provide them with this letter.

The applicable regulatory agencies are being notified.

Alternative solutions:

Please be advised that this product does not have any inventory for replacement. As such, DePuy Synthes Power Tools will provide a credit note for the affected article.

We understand that the removal of these products from the field may have an impact on your surgical schedule. As an alternative option to the credit note, the Colibri II (532.101) can also be operated with a specific battery and dedicated case (532.103 - Battery and 532.132 - Battery Casing with Locking for Lid). If you are interested in this option, please contact Customer Service.

We apologize for any inconvenience that this product removal may create and appreciate your cooperation with our request. Should you have any inquiries please do not hesitate to contact your DePuy Synthes sales consultant or contact person.

Thank you for your attention and cooperation.

Synthes GmbH



Anne Brisson
Senior QA Manager, Product Safety and
Performance

Cc:

Account Name: _____

URGENT NOTICE:
Field Safety Notice – Product Removal – R421630
Adapter for Colibri, for Electric Pen Drive (05.001.024)
Adapter, small, for Colibri (II) and Small Battery Drive (II) (05.001.108)

Product Descriptions	Part Number	Serial Numbers
Adapter for Colibri, for Electric Pen Drive	05.001.024	Lot# :1352144, 1468093, PA043998, 1467714, 1394645, 1544631, PA043998
Adapter, small, for Colibri (II) and Small Battery Drive (II)	05.001.108	See Attachment 1 for Serial Numbers

- We located the identified product in stock; returned quantity is documented below.
- We do not have any identified product in stock; returned quantity is zero. We have retained a copy of this letter for our records.

 RETURNED DEVICES (listing of serial numbers):

Name/Title (please print): _____

Address: _____

Phone Number: _____

Signature: _____ Date: _____

RGA # (If applicable): _____

Please complete and return this page your local DePuy Synthes contact person or sales consultant

Note: If the Verification Section is answered on behalf of more than one facility and/or individual, please clearly indicate the name and address of the facility and/or individual on this page of the notification.

Attachment 1

05.001.108 Adapter, small, for Colibri (II) and Small Battery Drive (II) Serial numbers											
1007	1125	1210	1262	1328	1381	1449	1519	1589	1659	1710	1761
1008	1126	1211	1263	1329	1382	1450	1520	1590	1660	1711	1762
1009	1127	1212	1264	1330	1383	1460	1521	1592	1662	1712	1763
1010	1131	1213	1265	1331	1384	1469	1522	1611	1663	1713	1764
1011	1132	1214	1266	1332	1385	1471	1523	1612	1664	1714	1765
1019	1134	1215	1267	1333	1386	1472	1524	1613	1665	1715	1766
1021	1135	1216	1268	1334	1387	1473	1525	1614	1666	1716	1767
1035	1137	1217	1269	1336	1388	1474	1526	1615	1667	1717	1768
1036	1138	1218	1270	1337	1389	1475	1527	1616	1668	1718	1769
1037	1139	1219	1271	1338	1390	1476	1528	1617	1669	1719	1770
1038	1140	1220	1272	1339	1391	1478	1529	1618	1670	1720	1771
1050	1147	1222	1273	1340	1392	1479	1530	1619	1671	1721	1772
1051	1150	1223	1274	1341	1393	1481	1551	1620	1672	1722	1773
1053	1152	1224	1275	1342	1394	1482	1552	1621	1673	1723	1774
1054	1153	1225	1276	1343	1395	1483	1553	1622	1674	1724	1775
1055	1154	1226	1277	1344	1396	1484	1554	1623	1675	1725	1776
1056	1156	1227	1278	1345	1397	1485	1555	1624	1676	1726	1777
1057	1157	1228	1279	1346	1398	1486	1556	1625	1677	1727	1778
1058	1158	1229	1281	1347	1399	1487	1557	1626	1678	1728	1779
1061	1159	1230	1282	1348	1400	1488	1558	1628	1679	1729	1780
1069	1160	1231	1283	1349	1409	1489	1559	1629	1680	1730	1781
1070	1161	1232	1284	1350	1411	1490	1560	1630	1681	1731	1782
1071	1162	1233	1285	1351	1412	1491	1561	1631	1682	1732	1783
1072	1163	1234	1286	1352	1413	1492	1562	1632	1683	1733	1784
1074	1164	1235	1287	1353	1414	1493	1563	1633	1684	1734	1785
1075	1165	1236	1288	1354	1415	1494	1564	1634	1685	1735	1786
1083	1166	1237	1289	1355	1416	1495	1565	1635	1686	1736	1787
1084	1167	1238	1290	1356	1417	1496	1566	1636	1687	1737	1788
1085	1168	1239	1298	1357	1418	1497	1567	1637	1688	1738	1789
1086	1169	1240	1299	1358	1419	1498	1568	1638	1689	1739	1790
1087	1170	1241	1300	1360	1420	1499	1569	1639	1690	1740	1791
1088	1191	1242	1307	1361	1421	1500	1570	1640	1691	1741	1792
1096	1192	1243	1308	1362	1431	1501	1571	1641	1692	1742	1793
1097	1193	1245	1309	1363	1432	1502	1572	1642	1693	1743	1794
1098	1194	1246	1310	1364	1433	1503	1573	1643	1694	1744	1795
1099	1195	1247	1311	1365	1434	1504	1574	1644	1695	1746	1796

05.001.108 Adapter, small, for Colibri (II) and Small Battery Drive (II) Serial numbers											
1101	1196	1248	1312	1366	1435	1505	1575	1645	1696	1747	1797
1102	1197	1249	1313	1367	1436	1506	1576	1646	1697	1748	1798
1103	1198	1250	1315	1368	1437	1507	1577	1647	1698	1749	1799
1104	1199	1251	1316	1369	1438	1508	1578	1648	1699	1750	1800
1105	1200	1252	1317	1371	1439	1509	1579	1649	1700	1751	1801
1106	1201	1253	1318	1372	1440	1510	1580	1650	1701	1752	1802
1107	1202	1254	1320	1373	1441	1511	1581	1651	1702	1753	1803
1108	1203	1255	1321	1374	1442	1512	1582	1652	1703	1754	1804
1109	1204	1256	1322	1375	1443	1513	1583	1653	1704	1755	1805
1110	1205	1257	1323	1376	1444	1514	1584	1654	1705	1756	1806
1112	1206	1258	1324	1377	1445	1515	1585	1655	1706	1757	1807
1113	1207	1259	1325	1378	1446	1516	1586	1656	1707	1758	1808
1122	1208	1260	1326	1379	1447	1517	1587	1657	1708	1759	1809
1123	1209	1261	1327	1380	1448	1518	1588	1658	1709	1760	1810
1811	1861	1917	1967	2019	2072	2141	2191	2241	2292	2343	2393
1812	1862	1918	1968	2020	2073	2142	2192	2242	2293	2344	2394
1813	1863	1919	1969	2021	2074	2143	2193	2243	2294	2345	2395
1814	1864	1920	1970	2022	2075	2144	2194	2244	2295	2346	2396
1815	1865	1921	1971	2023	2076	2145	2195	2245	2296	2347	2397
1816	1866	1922	1972	2024	2077	2146	2196	2246	2297	2348	2398
1817	1867	1923	1973	2025	2078	2147	2197	2247	2298	2349	2399
1818	1868	1924	1974	2026	2079	2148	2198	2248	2299	2350	2400
1819	1869	1925	1975	2027	2080	2149	2199	2249	2300	2351	2401
1820	1870	1926	1976	2028	2081	2150	2200	2250	2301	2352	2402
1821	1871	1927	1977	2029	2082	2151	2201	2251	2302	2353	2403
1822	1872	1928	1978	2030	2083	2152	2202	2252	2303	2354	2404
1823	1873	1929	1979	2031	2086	2153	2203	2253	2304	2355	2405
1824	1874	1930	1980	2032	2087	2154	2204	2254	2305	2356	2406
1825	1875	1931	1981	2033	2088	2155	2205	2255	2306	2357	2407
1826	1876	1932	1982	2034	2089	2156	2206	2256	2307	2358	2408
1827	1877	1933	1983	2035	2090	2157	2207	2257	2308	2359	2409
1828	1878	1934	1984	2036	2091	2158	2208	2258	2309	2360	1352ALT
1829	1879	1935	1986	2037	2092	2159	2209	2259	2310	2361	1483ALT
1830	1880	1936	1987	2038	2093	2160	2210	2260	2311	2362	1489ALT
1831	1881	1937	1988	2039	2094	2161	2211	2261	2312	2363	1490ALT
1832	1882	1938	1989	2040	2101	2162	2212	2262	2313	2364	1491ALT
1833	1883	1939	1990	2041	2102	2163	2213	2263	2314	2365	1493ALT
1834	1884	1940	1991	2042	2103	2164	2214	2264	2315	2366	2247ALT

05.001.108 Adapter, small, for Colibri (II) and Small Battery Drive (II) Serial numbers											
1835	1885	1941	1992	2043	2104	2165	2215	2265	2316	2367	2286ALT
1836	1886	1942	1993	2044	2105	2166	2216	2266	2317	2368	
1837	1887	1943	1994	2045	2106	2167	2217	2267	2318	2369	
1838	1888	1944	1995	2046	2107	2168	2218	2268	2319	2370	
1839	1889	1945	1996	2047	2108	2169	2219	2269	2320	2371	
1840	1890	1946	1997	2048	2109	2170	2220	2270	2321	2372	
1841	1891	1947	1998	2050	2110	2171	2221	2271	2322	2373	
1842	1892	1948	1999	2052	2121	2172	2222	2272	2323	2374	
1843	1893	1949	2000	2053	2122	2173	2223	2273	2324	2375	
1844	1894	1950	2001	2054	2123	2174	2224	2275	2325	2376	
1845	1901	1951	2003	2055	2124	2175	2225	2276	2326	2377	
1846	1902	1952	2004	2057	2125	2176	2226	2277	2327	2378	
1847	1903	1953	2005	2058	2126	2177	2227	2278	2328	2379	
1848	1904	1954	2006	2059	2127	2178	2228	2279	2329	2380	
1849	1905	1955	2007	2060	2129	2179	2229	2280	2330	2381	
1850	1906	1956	2008	2061	2130	2180	2230	2281	2331	2382	
1851	1907	1957	2009	2062	2131	2181	2231	2282	2332	2383	
1852	1908	1958	2010	2063	2132	2182	2232	2283	2333	2384	
1853	1909	1959	2011	2064	2133	2183	2233	2284	2334	2385	
1854	1910	1960	2012	2065	2134	2184	2234	2285	2335	2386	
1855	1911	1961	2013	2066	2135	2185	2235	2286	2336	2387	
1856	1912	1962	2014	2067	2136	2186	2236	2287	2337	2388	
1857	1913	1963	2015	2068	2137	2187	2237	2288	2338	2389	
1858	1914	1964	2016	2069	2138	2188	2238	2289	2340	2390	
1859	1915	1965	2017	2070	2139	2189	2239	2290	2341	2391	
1860	1916	1966	2018	2071	2140	2190	2240	2291	2342	2392	